

Efficacy of Foley's Catheter and the Effect of Histopathology, Age and Endometrial Thickness Relative to the Measured Outcomes in Menorrhagia

ZAHEERA SAADIA¹, ROBINA FARRUKH², MADIHA GHULAM RASOOL³

ABSTRACT

Introduction: Menorrhagia adversely affects the quality of life. Hysterectomy is the definitive treatment for menorrhagia however, a number of conservative alternatives are available.

Aim: Hysterectomy is the definitive treatment for menorrhagia however, a number of conservative alternatives are available. A thermal balloon is an effective but costly option. We used a Foley's catheter as an alternative to commercially available thermal balloons. If effective, it will provide a cheap alternative to the thermal balloon.

Materials and Methods: A Foley's catheter was placed in the uterine cavity for 10 minutes using 0.9% saline. The measured outcomes were amenorrhea, eumenorrhea, oligomenorrhea or failure of the therapy. Endometrial thickness, age and

INTRODUCTION

Menorrhagia is recurring heavy blood loss that is greater than the normal blood loss during a menstrual period [1]. It affects the quality of life of women physically, emotionally and socially. The condition can occur alone or in combination with other symptoms, such as fatigue, depression and impaired quality of work [2]. Despite menorrhagia being subjective, depending on how a woman can reasonably manage it, scientifically, it is defined as an approximate loss of blood that is greater than 80 ml, compared to the regular menses blood loss of 30-40 ml or if the menstrual bleeding lasts more than seven days [3]. The problem is evident mostly in girls who are starting to experience periods or when early menopause is approaching. Menorrhagia is highly associated with fibroids, hormonal problems, clotting disorders, intrauterine contraceptive devices, pelvic infections or even some anticoagulant drugs. However, if the bleeding is cyclical in pattern and no other pathology is evident, the cause is most likely endometrial factors, such as an altered production of prostaglandins with a deficiency of plasminogen activator factor [4-6]. The condition can be tested using ultrasound scans, endometrial sampling, blood tests, hysteroscopy and hydrosonography [7-10]. There are several available treatments that include the Levonorgestrel Intrauterine System (LNG-IUS), tranexamic acid tablets, anti-inflammatory painkillers, combined oral contraceptive pills, long-acting progestogen contraceptives and norethisterone [11,12]. Additionally, there are surgical methods that involve removing the lining of the uterus and a hysterectomy. The various modalities used in ablation include a thermal balloon, microwaves, cryotherapy, circulated hot fluid, radio frequency and electro surgery [13]. Endometrial ablations or resection using thermal balloon ablation is among the first surgical treatments that are used and this approach is the primary focus of this study. The first step during balloon thermal ablation procedure is the dilatation

endometrial biopsy results were also measured to determine if these variables had any effects on the outcome.

Results: Out of the total 42 participants, nearly half had amenorrhea (42.9%, n=18). Furthermore, 28.6% had oligomenorrhea (n=12) and 26.2% experienced eumenorrhea (n=11). Only one participant failed to respond (2.4%, n=1).

There were no differences in outcomes between the different forms of histopathology. This means that thermal balloon therapy is effective in causing amenorrhea. No significant relationships existed between participants' measured outcomes and a model containing predictor variables (age and endometrial thickness), R=0.313, R2=0.098, p=0.141.

Conclusion: A Foley's catheter is effective with reasonable measured outcomes in cases of menorrhagia.

Keywords: Amenorrhea, Menorrhagia, Thermal balloon

of the woman's cervix. This method involves inserting an instrument with a balloon at the tip that is then inflated using a pressurized heated solution that destroys the endometrium. Full endometrium thickness, superficial myometrium and basal glands are removed while retaining the uterus [14]. The procedure is very successful although repetition is required because it is not permanent. The procedure can prevent women from having children in future but should not be used as a birth control measure because some fertile women still have children after the operation. The duration of thermal balloon ablation is approximately 10-20 minutes and the woman may use anaesthesia and go home on the same day. Slight blood loss may follow the operation and the patient may even experience abdominal cramps. A number of devices are available for performing the procedure [14]. The procedure is said to be cost effective over hysterectomy [15]. First generation methods of Endometrial Ablation (EA) include roller ball and Trans Cervical Resection of the Endometrium (TCRE). Second generation devices include Microwave Endometrial Ablation (MEA) and Thermal Balloon Endometrial Ablation (TBEA) and, currently, the only third generation approach is the thermal Uterine Balloon Therapy (UBT) system [16,17]. Foley's catheters have been used by some researchers for endometrial ablation, but the available dataset is very small and needs further exploration [18]. All such devices are costly and not always available in third world countries. Therefore, we attempted to use the same principles of a thermal balloon with an easily available Foley's catheter as an alternative to commercially available thermal balloons. If successful, it may provide the cheapest alternative for conservative alternatives to hysterectomy.

We documented the efficacy of this therapy along with an exploration of the relationship of different forms of histopathology results with the measured outcomes. In addition, the relationship between age and endometrial thickness was also observed in relation to the measured outcomes.

MATERIALS AND METHODS

It was an interventional study and was conducted at Department of Obstetrics and Gynaecology for a period of six months between October 2014 and April 2015. The research protocol was approved by the relevant Institutional Review Board or Ethics Committee before the study began. All human participants gave written informed consent before the study began. The sample size was calculated using the WHO manual with an 80% power of test, 5% margin of error and the expected rate of amenorrhea to be 14% (least among all) in patients with intractable menorrhagia after thermal balloon ablation.

Patients between 39–52 years of age who had intractable menorrhagia by the preoperational definition were included in the study. Patients who planned to have additional children, who had endometrial pathologies like fibroids or endometrial polyps, abnormal endometrial histopathology, history of previous pelvic inflammatory disease and patients with a scarred uterus were excluded from the study.

After approval from the Hospital Ethical Board, 42 patients who fulfilled the selection criteria and gave written consent were enrolled in the study. All patients received 1 gram ceftriaxone, intravenously 30 minutes before the procedure as a prophylactic antibiotic. A silicone Foley's catheter was placed in the uterine cavity and the balloon was inflated with boiling 0.9% saline until the maximum capacity of the uterine cavity was reached. Amount of boiling water was variable from 30-40 cc depending upon uterine capacity. Water once instilled was kept for 3 min. This procedure was repeated total of three times. Foley's catheter was inflated for a total of three times and then removed. Before thermal ablation all patients underwent pipelle endometrial sampling to exclude malignancy. Procedure of endometrial curettage was carried out under regional anaesthesia (saddle block), before starting thermal ablation in all patients so as to remove maximum endometrium. Postoperatively, all patients received a single shot of an intramuscular diclofenac sodium injection and were followed-up at the outpatient clinic 12 weeks after the procedure. Patients were interviewed and menstrual outcomes were noted in the patient's proforma attached to their file. All the patients were followed by the same consultant and all histopathologies were acquired from the same laboratory to eliminate bias. Confounding variables were controlled by exclusion.

STATISTICAL ANALYSIS

Inferential statistics were used to draw conclusions from the samples that were tested. The Statistical Package for the Social Sciences (SPSS, version 20.0) was used to code and tabulate scores collected from the survey and provide summarized values where applicable, including the mean, central tendency, variance and standard deviation. A chi-square comparison of proportions tests, chi-square tests of independence and multiple regression analyses were used to evaluate three research questions.

RESULTS

Research Questions

The research questions were as follows:

- 1. Research Question 1 (RQ1): Would women who presented with menorrhagia respond to endometrial ablation (e.g., develop amenorrhea, eumenorrhea, oligomenorrhea or a failed response)?
- Research Question 2 (RQ2): Do different forms of histopathology results have any relationship to the measured outcomes?
- **3. Research Question 3 (RQ3):** Does age or endometrial thickness have any relationship to the measured outcomes?

Demographics: Data were collected from 42 women. Specifically,

85.7% of the participants were house wives (n=36) and the remaining 14.3% were professionals (n=6). Furthermore, the majority of participants had a primary level of education (52.4%, n = 22), 28.6% were illiterate (n=12) and the remaining 19.0% had a university level of education (n=8). [Table/Fig-1] depicted frequency and percent statistics of participants' occupations and their level of education. [Table/Fig-2,3] describe the frequency of endometrial thickness, size of the uterus and histopathology results obtained before the procedure.

Demographic	Frequency (n)	Percent (%)				
Occupation						
House wife	36	85.7				
Professionals	6	14.3				
Total	42	100.0				
Level of education						
Illiterate	12	28.6				
Primary level	22	52.4				
University level	8	19.0				
Total	42	100.0				

[Table/Fig-1]: Frequency and percent statistics for participants' occupations and levels of education. Total N = 42

Demographic	Frequency (n)	Percent (%)
Endometrial thickness		
5 mm and less	3	7.1
6 - 10 mm	8	19.0
Above 10 mm	31	73.8
Total	42	100.0
Clinical size of the uterus		
Normal	6	14.3
8 weeks	15	35.7
10 weeks	16	38.1
12 weeks	5	11.9
Total	42	100.0
[Table/Fig-2]: Frequency and perce	ent statistics of parti	cipants' endometrial

Total N = 42

Analysis of research question 1: Research question 1 was evaluated using a chi-square comparison of proportion tests to determine if there were significant differences in the outcomes of women who undertook an endometrial ablation. The dependent variable was participants' measured outcome after receiving an endometrial ablation. Specifically, the four possible outcomes included amenorrhea (absence of menstruation), oligomenorrhea (light/infrequency menstruation), eumenorrhea (normal menstruation) or a failure to respond.

As displayed in [Table/Fig-4], nearly half of the participants' outcomes resulted in amenorrhea (42.9%, n=18). Furthermore, 28.6% of participants' outcomes resulted in oligomenorrhea (n=12) and 26.2% resulted in eumenorrhea (n=11). Finally, only one participant failed to respond to the treatment (2.4%, n=1). Displayed in [Table/Fig-4] are the frequency and percent statistics of participants' measured outcomes.

Results of research question 1:

Ho1: There were no significant differences in the outcomes of women who undertook an endometrial ablation.

Ha1: There are significant differences in the outcomes of women who undertook an endometrial ablation.

Research question 1 was conducted using a chi-square comparison of proportion tests to determine if there were significant differences in the outcomes of women who undertook an endometrial ablation.

Demographic	Frequency (n)	Percent (%)
Histopathology		
Proliferative phase	17	40.5
Secretory phase	10	23.8
Cystic hyperplasia	10	23.8
Adenomatous hyperplasia	5	11.9
Total	42	100.0
Outcome		
Amenorrhea	18	42.9
Oligomenorrhea	12	28.6
Eumenorrhea	11	26.2
Failed treatment	1	2.4
Total	42	100.0
Complication after procedure		
Bleeding	6	14.3
Infection	6	14.3
Pain	7	16.7
Irregular spotting	3	7.1
Nil	20	47.6
Total	42	100.0

[Table/Fig-3]: Frequency and percent statistics of participants' histopathology, outcome and complications after procedures. Total N = 42

Measured Outcome	Frequency (n)	Percent (%)		
Amenorrhea	18	42.9		
Oligomenorrhea	12	28.6		
Eumenorrhea	11	26.2		
Failed to respond	1	2.4		
Total	42	100.0		
[Table/Fig-4]: Frequency outcomes.	and percent statistics of	participants' measured		

The results indicated that only one significant comparison of proportions existed between those with amenorrhea outcomes compared to those that failed to respond to the treatment, this means that thermal balloon therapy is effective in all forms of endometrial pathologies. There was a significantly higher frequency of amenorrhea outcomes (n = 18) compared to those who failed to respond to the treatment (n = 1). There were no other significant differences between participants' outcomes. Displayed in [Table/ Fig-5] are the summary statistics of the chi-square comparison of the proportions tests used to evaluate research question 1.

Analysis of research question 2: Research question 2 was evaluated using a chi-square test of independence to determine if there were significant differences in participants' measured outcomes between different forms of histopathology. The dependent variable was participants' outcomes as measured by four levels including amenorrhea, oligomenorrhea, eumenorrhea and failed treatments. The independent variable was participants' type of histopathology, including proliferative phase, secretory phase, cystic hyperplasia and adenomatous hyperplasia.

Results of research question 2:

Ho2: There were no significant differences in participants' measured outcomes between their different forms of histopathology.

Ha2: There were significant differences in participants' measured outcomes between their different forms of histopathology.

Research question 2 was evaluated using a chi-square test of independence to determine if there were significant differences in the participants' measured outcomes between different forms of histopathology. The results indicated that thermal balloon therapy is effective in all forms of endometrial pathologies. Thus, the null

hypothesis for research question 2 was retained. A frequency crosses tabulation of participants' measured outcomes and forms of histopathology are displayed in [Table/Fig-6].

Source of Comparison	% Differ-	χ ² ο	df	Sig.	95% Confidence Interval	
	ence		(p)	Lower	Upper	
Amenorrhea * Oligomenorrhea	6%	0.216	1	0.642	-11.075	22.908
Amenorrhea * Eumenorrhea	7%	0.361	1	0.548	-9.876	23.712
Amenorrhea * Failed to respond	17%	5.220	1	0.022	3.279	31.948
Oligomenorrhea * Eumenorrhea	1%	0.039	1	0.843	-14.675	16.681
Oligomenorrhea * Failed to respond	11%	2.567	1	0.109	-1.214	24.786
Eumenorrhea * Failed to respond	10%	2.161	1	0.142	-1.941	23.538
[Table/Fig-5]: Summary of results from the chi-square comparison of proportion tests conducted for research.						

Measured Outcome								
Form of Histopa- thology	Amenor- rhea	Oligom- enorrhea	Eumen- orrhea	Failed treatment	Total			
Proliferative phase	6	6	4	1	17			
Secretory phase	4	3	3	0	10			
Cystic hyperplasia	6	2	2	0	10			
Adenomatous hyperplasia	2	1	2	0	5			
Total	18	12	11	1	42			
[Table/Fig-6]: Cross tabulation of participants' measured outcome and forms of histopathology.								

Analysis of research question 3: Research question 3 was evaluated using multiple regression analysis to determine if a significant relationship existed between participants' measured outcomes and their age and endometrial thickness. The criterion variable was participants' measured outcomes (amenorrhea, oligomenorrhea, eumenorrhea and failed treatment). For the multiple regression analysis, the criterion variable was considered to be measured on an ordinal scale due to the increases in the measured outcomes (1 = amenorrhea - absence of menstruation, 2 = oligomenorrhea - light/infrequency menstruation and 3 = eumenorrhea -normal menstruation). However, since the outcome "failed to respond" does not fit within the ordinal scale, the one participant who failed to respond to the treatment (ID #39) was removed from the analysis. The predictor variables were participants' age and endometrial thickness.

Data cleaning: Data were collected from a sample of 42 women who underwent an endometrial ablation. Before the assumptions were assessed, the data were screened for missing data, univariate outliers and multivariate outliers. Missing data were investigated using frequency counts and one case (ID #39) was found and removed from the analysis as defined in the previous paragraph. The distributions were evaluated for univariate and multivariate outliers and no cases were found within the distributions. Thus, responses from 42 participants were received and 41 were evaluated with the multiple regression analysis for research question 3 (N = 41). Descriptive statistics of the criterion and predictor variables are displayed in [Table/Fig-7].

Parametric assumptions: Prior to analysing the research question, data screening was undertaken to ensure the variables of interest met appropriate statistical assumptions. Thus, the criterion and predictor variables were first evaluated for normality, linearity, homoscedasticity and multicollinearity. Results indicated that no distributions violated the assumptions of linearity, homoscedasticity and multicollinearity. However, the distribution of endometrial thickness was found to be significantly skewed, skewness = -1.655, z-skew = -4.485. Skewness and kurtosis statistics of participants' age, endometrial thickness and measured outcome are shown in [Table/Fig-8].

The distribution was transformed using a square root transformation. However, results from the multiple regression analysis using the transformed scores were similar to the results found using the untransformed scores. Therefore, the untransformed endometrial thickness scores were used to evaluate research question 3.

Results of research question 3:

Ho3: There is no significant relationship between participants' measured outcomes and their age and endometrial thickness.

Ha3: There were significant relationships between participants' measured outcomes and their age and endometrial thickness.

Research question 3 was evaluated using multiple regression analysis to determine if a significant relationship existed between participants' measured outcomes and their age and endometrial thickness. The results indicated that no significant relationships existed between participants' measured outcomes and a model containing two predictor variables, R = 0.313, R2 = 0.098, F(2, 38)= 2.060, p = 0.141. Thus, the null hypothesis for research question 3 was retained. A model summary of the regression analysis is displayed in [Table/Fig-9].

Variable	Min	Max	Mean	Std. Devia- tion	Skew- ness	Kurtosis	
Age	38	51	46.270	3.413	-0.598	-0.658	
Endometrial Thickness	1	3	2.660	0.617	-1.655	1.700	
Outcome	1	3	1.830	0.834	0.338	-1.484	
[Table/Fig-7]: Descriptive statistics for participants' age endometrial thickness and							

measured outcomes. Total N = 41

Demographic	Skew- ness	Skew Std. Error	z-skew	Kurto- sis	Kurto- sis Std. Error	z-kurto- sis
Age	-0.598	0.369	-1.621	-0.658	0.724	-0.909
Endometrial Thickness	-1.655	0.369	-4.485	1.700	0.724	2.348
Outcome	0.338	0.369	0.916	-1.484	0.724	-2.050
[Table/Fig-8]: Skewness and kurtosis statistics of participants' age, endometrial						

thickness and measured outcome. Total N = 41

Source	R	R ²	Standard Error	F	Sig. (p)	
Omnibus	0.313	0.098	0.812	2.060	0.141	
	Unstand- ardized	Coefficients	Standardized Coefficients			
Source	В	Std. Error	Beta	t	Sig. (p)	Part Corre- lation
(Constant)	-1.708	1.821		-0.938	0.354	
Age	0.063	0.038	0.259	1.680	0.101	0.259
Endometrial Thickness	0.230	0.208	0.170	1.104	0.277	0.170

[Table/Fig-9]: Model summary of regression for research question 3.

 $\frac{1}{2} = \frac{1}{2} = \frac{1}$

DISCUSSION

According to the statistical presented in [Table/Fig-5], the significant differences between amenorrhea and oligomenorrhea were slightly low at 6% and 7%, respectively, which indicated that they coincided with the fact that the thermal balloon is an effective measure of treating menorrhagia. The likelihood of the procedure failing is slightly

The high success rate of thermal balloon ablation is indicated by an immense reduction of menses for the condition amenorrhea. Amenorrhea is the complete absence of a menstrual period that may develop, which makes the procedure be a partial birth control measure. Additionally, eumenorrhea may develop, which is a normal menstrual period. A different combination that may occur is oligomenorrhea amenorrhea, eumenorrhea amenorrhea and eumenorrhea oligomenorrhea. Rarely, treatment may fail to correct the condition of menorrhagia. The success rate is determined by the high rate of amenorrhea, eumenorrhea and oligomenorrhea [18].

The widespread use of thermal balloon ablation is due to its easiness and simplicity with little complications developing after the procedure. The chief challenge, however, is the expensive nature of the machine and the disposable balloon making the treatment unreachable to most of the economically challenged population [19]. Improvement of the procedure increased the confidence and satisfaction of the patients. The participants' age, endometrial thickness and histopathology type did not affect the measured outcome. Therefore, the procedure has the potential to be used irrespective of the benign endometrial biopsy results and in all the measured age groups (39–52 years).

CONCLUSION

The findings of this study support our hypothesis that a Foley's catheter can be used for thermal ablation of the endometrium. It is effective with reasonably measured outcomes. It has the potential to be used as an alternative to costly thermal ablation devices. Menorrhagia is a common problem and needs conservative alternatives for hysterectomy to be explored, especially for thirdworld countries that are economically challenged.

ACKNOWLEDGEMENTS

The author is grateful to Sir Ganga Ram Hospital staff and administration for their support. No financial grant or funding was received for this study.

REFERENCES

- Oehler MK, Rees MC. Menorrhagia: an update. Acta Obstet Gynecol Scand. 2003;82:405–22.
- [2] Friedman AJ, Chen Z, Ford P, Johnson CA, Lopez AM, Shander A, et al. Iron deficiency anemia in women across the life span. J Womens Health (Larchmt). 2012;21:1282–89.
- [3] Marret H, Fauconnier A, Chabbert-Buffet N, Cravello L, Golfier F, Gondry J, et al. Clinical practice guidelines on menorrhagia: management of abnormal uterine bleeding before menopause. Eur J Obstet Gynecol Reprod Biol. 2010;152:133– 37.
- [4] Bahamondes L, Ali M. Recent advances in managing and understanding menstrual disorders. F1000 Prime. Reproduction. 2015;7:33.
- [5] Gleeson NC. Cyclic changes in endometrial tissue plasminogen activator and plasminogen activator inhibitor type 1 in women with normal menstruation and essential menorrhagia. Am J Obstet Gynecol. 1994;171:178–83.
- [6] Smith S, Abel MH, Kelly RW, Baird DT. A role for prostacyclin (PGI2) in excessive menstrual bleeding. Lancet. 1981;317:522–24.
- [7] Kanthi JM, Remadevi C, Sumathy S, Sharma D, Sreedhar S, Jose A. Clinical study of endometrial polyp and role of diagnostic hysteroscopy and blind avulsion of polyp. J Clin Diagn Res. 2016;10:QC01–04.
- [8] Timmerman D, Verguts J, Konstantinovic ML, Moerman P, Van Schoubroeck D, Deprest J, et al. The pedicle artery sign based on sonography with color Doppler imaging can replace second-stage tests in women with abnormal vaginal bleeding. Ultrasound Obstet Gynecol. 2003;22:166–71.
- [9] Guven MA, Bese T, Demirkiran F. Comparison of hydrosonography and transvaginal ultrasonography in the detection of intracavitary pathologies in women with abnormal uterine bleeding. Int J Gynecol Cancer. 2004;14:57–63.
- [10] National Collaborating Centre for Women's and Children's Health (UK). Heavy Menstrual Bleeding. London: RCOG Press, 2007.
- [11] Prentice A. Medical management of menorrhagia. West J Med. 2000;172:253– 55.

- [12] Maybin JA, Critchley HO. Medical management of heavy menstrual bleeding. Womens Health (Lond). 2016;12:27–34.
- Marjoribanks J, Lethaby A, Farquhar C. Surgery versus medical therapy for heavy menstrual bleeding. Cochrane Database Syst Rev. 2016;(1):CD003855.
- [14] Lucot JP, Coulon C, Collinet P, Cosson M, Vinatier D. Surgical therapeutic management for menorrhagia. J Gynecol Obstet Biol Reprod. 2008;37:S398-S404.
- [15] Sculpher MJ, Bryan S, Dwyer N, Hutton J, Stirrat GM. An economic evaluation of transcervical endometrial resection versus abdominal hysterectomy for the treatment of menorrhagia. Br J Obstet Gynaecol. 1993;100:244–52.
- [16] Garside R, Stein K, Wyatt K, Round A, Price A. The effectiveness and costeffectiveness of microwave and thermal balloon endometrial ablation for heavy

menstrual bleeding: a systematic review and economic modelling. Health Technol Assess. 2004;8:iii,1-iii155.

- [17] Garza-Leal J, Pena A, Donovan A, Charles JR, Romanowski C, lie B et al. Clinical evaluation of a third-generation thermal uterine balloon therapy system for menorrhagia coupled with curettage. J Minim Invasive Gynecol. 2010;17:82– 90.
- [18] El Hameed AA. 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 Fertil Soc J. 2012;17:116–21.
- [19] Pai RD. Thermal balloon endometrial ablation in dysfunctional uterine bleeding. J Gynecol Endosc Surg. 2009;1:31–33.

PARTICULARS OF CONTRIBUTORS:

- 1. Associate Professor, Department of Obstetrics and Gynaecology, Qassim University, Buraidah, Al Qassim, Saudi Arabia.
- 2. Associate Professor, Department of Obstetrics and Gynaecology, Fatima Jinnah Medical College, Lahore, Punjab, Pakistan.
- 3. Medical Officer, Department of Obstetrics and Gynaecology, Sir Ganga Ram Hospital, Lahore, Punjab, Pakistan.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Zaheera Saadia,

Alrajhi building 4, Apartment 108 King Khalid Road, Buraidah, Al Qassim, Saudi Arabia. E-mail: zaheerasaadia@hotmail.com

FINANCIAL OR OTHER COMPETING INTERESTS: None.

Date of Submission: Jan 08, 2017 Date of Peer Review: Apr 25, 2017 Date of Acceptance: May 06, 2017 Date of Publishing: Jul 01, 2017