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The Role of Intrauterine Bigatti Shaver in Removal of Retained Products of Conception in Sample of Iraqi Women

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ABSTRACT

Background & Objective: Intrauterine Bigatti shaver has several benefits over classical methods like dilation and curettage. It offers a more precise tissue removal, facilitating improved visualization to the uterine lining .This procedure is deemed safer, and consumes less time and effort. To highlight the effectiveness of the Bigatti Shaver as a valuable treatment option particularly in patients with miscarriages or complicated dilatation and curettage.

Materials & Methods: Fifty women aged between 18-44 years underwent placental remnant removal using Bigatti Shaver. The primary outcomes include complete removal of retained products of conception (RPOC), procedure time and possible complications while secondary outcomes focused on patient satisfaction and necessity for further intervention.

Results: The Bigatti Shaver demonstrates remarkable success in completely removing RPOC in all 50 women (100%). The size of placental remnants varied between 15-33 mm. The resection time has a range of 22-110 seconds. Results showed a positive correlation between age and size (r=0.552), age and resection time (r=0.331) .additionally size and resection time (r=0.559), size and infection (r=0.415) and time and infection (r=0.470). Follow up of postoperative patients revealed mild infection in two and mild vaginal bleeding in 4 patients.

Conclusion: The Bigatti Shaver (IBS) is confirmed to be a safe and effective procedure for the removal of RPOC. Overall, patient satisfaction was highly encouraging.

Keywords: Retained products of conception, Intrauterine Bigatti Shaver

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1. Introduction

Retained Products Of Conception (RPOC) is a common complication, could be placental debris or fetal material or both that persist inside uterine cavity after delivery, terminated pregnancy or a miscarriage **(1)**. The risk of RPOC is reported to threaten 17% of first trimester miscarriages, 40% of second trimester miscarriages compared to 3% of full-term deliveries **(2,3)**.

Few patients with retained products of conception could be asymptomatic but majority experience symptoms like vaginal bleeding, which is noticed in 80% of patients, continued heavy bleeding if left untreated end with serious complications, fever is reported in 5%, abdominal or pelvic pain in 5%. The fever and abdominal or pelvic pain and tenderness could be signs of an infection in the retained products **(4)**.

Definitive management of patients presented with RPOC will depend on the amount of bleeding, hemodynamic variability, infection and could be patient choice. Ideal management should lead to complete emptying of the uterine cavity without damage to the endometrium; this seems a priority in women with reproductive desires **(5)**. Ultrasound is necessary for more accurate diagnosis because it can precisely tell if placental remnants require surgical intervention or only conservative management **(6)**.

Several methods have been used for the removal of RPOC, including manual vacuum aspiration, Dilation And Curettage (D&C) and hysteroscopy **(7)**. Dilation and curettage are commonly and traditionally used as management options but when it is compared with operative hysteroscopy it conveys high risk of infection, Intrauterine Adhesions (IUAs), incomplete evacuation and it may result in uterine perforation or bowel injury **(8,9)**. A less invasive procedure which has

been used in cases of bleeding managements after abortion or delivery 30 years ago is the operative hysteroscopy that permits placental remnants removal under direct vision thus minimizing complications **(10,11)**.

The new Bigatti Shaver (IBS) is a hysteroscopic instrument that uses a rotating blade to shave and selectively remove remnants of conception under direct vision. This technique includes a small 8.5mm sheath diameter with undetectable damage to healthy endometrium, no thermal injury and no adhesion .IBS has already proved to be a safe and effective technique for RPOC removal in many countries **(12,13)**. However, there is limited and few research on its use for removal of RPOC in our local context. We hope with this study to provide further evidence on the potential benefits of the Bigatti Shaver in the management of RPOC and contribute to the development of current alternatives to traditional methods of D&C on the basis of safety and achievement rate.

2. Materials and Methods

This prospective study aims to assess the safety and efficacy of the Bigatti Shaver for the removal of retained products of conception in women who have experienced a miscarriage or termination of pregnancy.

Patients

The study had been conducted from Sep 2022 to Sep 2023 on fifty women aged 18-45 years who had been diagnosed with RPOC following a miscarriage or terminated pregnancy. Exclusions were made for women with severe pelvic infection or cervical stenosis. Postoperative histopathological examination to confirm the presence of placental remnants was done in 48 patients (96%). A comprehensive gynecological history was obtained from each patient enrolled in this study

Patients were referred with varied symptoms, the majority presented with abnormal uterine bleeding (40 patients=80%) while few reported amenorrhea or subfertility and the rest were asymptomatic. Among 50 patients 30 had history of normal vaginal delivery (NVD), 13 with previous cesarean section (C/S) and 7 with history of previous Dilatation And Curettage (D&C).

Each women underwent preoperative ultrasound examination (abdominal or transvaginal) the choice of anesthesia (local or general) depend on patient's will and medical parameters. The time of the procedure was recorded.

Data analysis

Descriptive statistical analysis using ANOVA test and Correlation coefficient will summarize the demographic and clinical characteristics of the study population, mean age, size of RPOC and resection time calculated as in (Table 1.2.3).

Surgical procedure

After dilatation of cervix with number 8 Hegar diliator, normal physiological saline served as irrigation and distention media. In all patients the Bigatti Shaver (Karl Storz GmbH & Co. of Tuttlingen) (Figure 1) was used for removal and tissue chips were cleaned during the resection, the samples collected for histopathological examination.

Figures 2, 3, 4, 5 demonstrate surgical intervention with Bigatti shaver for removal of RPOC.

3. Results

Fifty women enrolled in the study with mean age of 29.62±8.214 years, mean size of RPOC 23.24±5.77 mm and mean time calculated to end the procedure is 57.60±22.569 seconds as shown in Table 1.

Table 1: Mean age, size and time of study population

	Range			
	N	**Minimum**	**Maximum**	**Mean ± Std**
Age (yrs.)	50	18	44	29.62±8.214
Size (mm)	50	15	34	23.24±5.777
Time (sec)	50	22	110	57.60±22.569
Total	50			

All patients were subjected to complete removal of RPOC using the Bigatti Shaver to achieve full evacuation without major complications, high removal rate, and relatively short time as seen in Table 1.

The uterine cavity was completely free from placental remnants at the end of the procedure. Patients were kept under observation for a few hours after the procedure and then discharged on the same day, with follow-up instructions for 5-6 weeks.

After the first post-operative menstrual period, all patients underwent a transvaginal ultrasound to assess the endometrial cavity and to confirm the absence of

any placental remnants. On follow up the ultrasound confirmed a smooth endometrium, no residual products no need for further evacuation, results showed that the incidence of complications associated with the use of the Bigatti Shaver is low and easily managed, from 50 patients 2 had mild infection, 4 with mild vaginal bleeding and no case with uterine perforation was documented Table 2.

The correlation coefficients between age, size and time compared with complications (infection and vaginal bleeding) were not significant (Correlation Coefficient is significant at the 0.01 level).

Results found a moderately strong positive correlation between age and size (r=0.552) (Correlation is significant at the 0.05 level), age and time (r=0.331) and a strong positive correlation was detected between size and time (r=0.559), size and the likelihood of infection (r=0.415), and time and the likelihood of infection (r=0.470), as shown in Table 3.

Figure 1: Intrauterine Bigatti Shaver (Karl Storz GmbH & Co. of Tuttlingen).

Figures: 2, 3, 4 Demonstrate patients with RPOC confirmed by ultrasound before and after operation with Intrauterine Bigatti Shaver.

Table 2. Complications with intrauterine Bigatti shaver

Complication	No	Infection%	Vaginal bleeding%	Uterine perforation%
Infection (mild)	2	4%		
Vaginal bleeding	4		8%	
Uterine perforation	0			0%



Figure 1. Intrauterine Bigatti Shaver (Karl Storz GmbH & Co. of Tuttlingen)

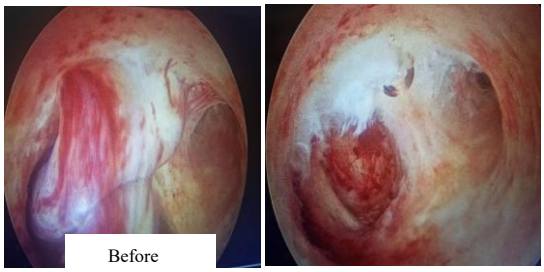


Figure 2. 33-year-old patient, para 2 with placental ruminant 30 mm size after 15 weeks pregnancy presented with abnormal vaginal bleeding, women had septated uterus.



Figure 3. 32-year-old patient, 17 weeks pregnant with RPOC 34mm size

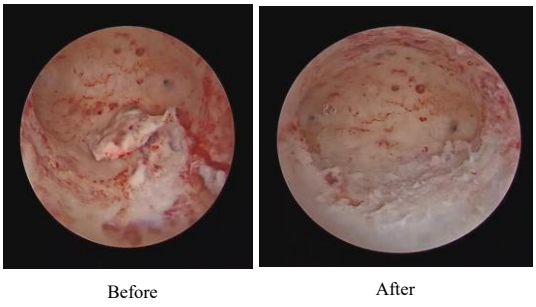


Figure 4. 36-year-old patient 14 weeks pregnant presented with RPOC 28 mm size

Table 3. Correlations between age, size, time with complications

		Age yrs.	Size-mm	Time-s	Infection	Vag-bleeding
Age years	Correlation Coefficient	1.000	.552**	.331*	0.064	-0.025
	Sig. (2-tailed)		0.000	0.019	0.659	0.865
	N	50	50	50	50	50
Size-mm	Correlation Coefficient	0.552**	1.000	0.559**	.415**	0.118
	Sig. (2-tailed)	0.000		0.000	0.003	0.416
	N	50	50	50	50	50
Time-s	Correlation Coefficient	.331*	.559**	1.000	.470**	-0.015
	Sig. (2-tailed)	0.019	0.000		0.001	0.917
	N	50	50	50	50	50
Infection	Correlation Coefficient	0.064	0.415**	0.470**	1.000	0.273
	Sig. (2-tailed)	0.659	0.003	0.001		0.055
	N	50	50	50	50	50
Vag-bleeding	Correlation Coefficient	-0.025	0.118	-0.015	0.273	1.000
	Sig. (2-tailed)	0.865	0.416	0.917	0.055	
	N	50	50	50	50	50

Note: The significance levels (**) indicate strong evidence of correlation, while (*) indicates moderate evidence of correlation. Top of Form

** Correlation is significant at the 0.01 level (2-tailed). * Correlation is significant at the 0.05 level (2-tailed)

4. Discussion

Recent studies have shown that women with miscarriage, misoprostol/mifepristone is given and considered as an effective drug used as alternative for curettage, most patients underwent impulsive expulsion of the placental remnants within two to four weeks **(9)**, but in those women ultrasound findings during follow-up usually reveal incomplete evacuation of uterine Retained Products Of Conception (RPOC), necessitating further intervention for evacuation **(14,15)**.

Most of our patients 40/50 (80%) RPOC were diagnosed by trans vaginal ultrasound showcasing as an echogenic focus in a thickened endometrium, more than 10 mm in size , and these findings agree with previous studies **(6,16,17)**. D&C has been the primary choice for the management of RPOC, but the risk of Intrauterine Adhesions (IUTs) increases up to 40% with repeated procedures **(10)**.

The hysteroscopic procedure is an enhanced method for RPOC management, provide direct visualization of uterus, complete evacuation with minimum complications and availability therefore it is reasonable to assume that direct visualization will reduce the risk of uterine perforation. Plus, the risk of incomplete removal of retained placenta will also be decreased, certainly leading to fewer IUA's **(18)**.

Results reveal a moderately strong positive correlation between age and RPOC size of RPOC suggesting that as age increases, the size tends to increase as well similarly there is a moderate positive correlation between age and procedure time, as age increases, the time also tends to increase. In addition to strong positive correlation between size and time when size increases, the time also tends to elongate. Also, larger sizes of RPOC may be associated with a higher risk of infections and longer procedures.

We agree with many other studies that the new shaver technique with the IBS method, when inserted into the uterine cavity, it is left in place for the entire duration of the procedure thus providing an excellent removal of tissue chips at the same time as the resection. By using saline solution the risk of intravasation will be reduced ,ensuring low fluid deficit and fast procedure, easy collection of tissues for pathology and convenience of shaver reusability. Ultimately the technique allows for precise clean surgery. Patient satisfaction with the Bigatti Shaver is reported to be high with most patients experiencing no pain or little discomfort during the procedure, the

success rates, procedure time, and complications are better with most patients achieving complete removal on the first attempt.

5. Conclusion

The Bigatti Shaver proves to be a safe and effective method for the removal of RPOC. The high complete removal rate, low complication incidence, and positive patient feedback make it the best preferable alternative to traditional methods like D&C.

6. Declarations

Acknowledgments

Authors appreciate and thanks all female patients collaborate in this study.

Ethical Considerations

The research protocol was officially signed by the Ethical Committee of Al- Zahraa College of Medicine at University of Basrah (approval number Ant-010, date 26/9/2022). Informed consent was obtained from all participants.

Authors' Contributions

Raya M Al Hassan and Nawal M Abdulla suggested the presented idea, the hypothesis and applicable points, both conducted the experiment, Nawal M Abdullah supervised, achieved the calculations. complete the analytic approaches and provided the logistic support to the manuscript. Both authors reviewed the manuscript, approved the final print and are responsible for contents and similarity index of the manuscript.

Conflict of Interest

No conflict of interest

Fund or Financial Support

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