Outcomes of Mechanical Resection of Endometrial Polyps and Submucosal Fibroids Through TruClear™ Hysteroscopy

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ABSTRACT

Objective: To assess the efficacy of mechanical resection through TruClear™ hysteroscopy in patients with endometrial polyps and submucosal fibroids.

Study Design: Descriptive study.

Place and Duration of the Study: Department of Obstetrics and Gynaecology, Shifa International Hospital, Islamabad, Pakistan, from June 2018 to 2022.

Methodology: Patients diagnosed with endometrial polyps and submucosal fibroids confirmed by abdominal or transvaginal ultrasonography were included. Patients having a history of congestive cardiac failure, chronic kidney disease, and bleeding diathesis were excluded from the study. Data about the complete removal of pathology (endometrial polyps and submucosal fibroids), mean operating time, and postoperative complications such as bleeding and perforation were extracted. The follow-up was set up to 6 months after the procedure.

Results: The average age of the 45 patients was 35.62 ± 7.46 years. Heavy menstrual bleeding was the most prevalent symptom, seen in 73.3% of cases, followed by irregular vaginal bleeding (IVB) in 11.1% of cases. The most frequent disease identified by sonography was a polyp in 21 (47%) instances, followed by submucosal fibroids in 12 (27%) cases, mixed pathology in 10 (22%), and malignancy in 2 (4%) cases. The overall average operative time was 36.46 ± 24.94 minutes. A hundred percent removal of lesions was observed in this study. Persistent symptoms were observed in 13% of patients after the surgery so they were treated with other interventions. The most common intervention was an intrauterine hormonal device. Intraoperative bleeding was observed in only one patient and was managed by intraoperative intrauterine balloon insertion. The recurrence rate was 8.9% (4/45).

Conclusion: TruClear™ hysteroscopy showed a major advantage in the successful and complete removal of the pathology, low operation time, and complications.

Key Words: *Fibroids, Hysteroscopy, Polyps, Endometrial resection, Menstrual bleeding.*

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INTRODUCTION

One of the most common clinical presentations in the gynaecological clinic is abnormal uterine bleeding (AUB), which affects up to 30% of women.[1] According to the International Federation of Gynaecology and Obstetrics (FIGO) classification, the causes of AUB include structural and functional disorders. Among these structural causes, endometrial polyps and submucosal leiomyoma contribute to the most common causes of AUB.[2] Polyps are overgrowths of endometrial glands that protrude into the uterine cavity.[2]

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They are found in all reproductive and non-reproductive age groups,[3] and have a myriad of symptoms, with incidental findings reported in 18% of premenopausal women and 56% of postmenopausal women.[4] AUB affects 13-15% of premenopausal women and 30% of postmenopausal women.[5]

Submucosal leiomyomas are derived from myometrial cells and protrude into the uterine cavity. The extent of protrusion is described by the FIGO / European Society of Hysteroscopy classification system, wherein a Type 0 leiomyoma is within the endometrium, Type 1 extends less than 50% into the myometrium, and Type 2 extends beyond 50% of the myometrium.[2] Though most women with leiomyomas are asymptomatic, approximately 25% present with serious symptoms.[6] AUB is the most common symptom among symptomatic women with uterine fibroid, occurring in approximately 26-29% of patients.[7,8] The prevalence of submucosal fibroids is 8.2% in the general population which indicates a significant burden of illness.[9]

Many options are available for the diagnosis of endometrial polyps and submucosal fibroids. Transvaginal ultrasonography (TVUS) is one of them, with an overall sensitivity, specificity, positive predictive value, and negative predictive value, and accuracy of 69%, 51%, 73%, 46%, and 63%, respectively.[10] The colour-flow or power Doppler improves the diagnostic capability of TVUS.[11-13] Hysteroscopy is both diagnostic and therapeutic.[14] When expertise and facilities allow, the targeted removal of pathology under direct vision enables the complete resection of pathology and reduces the risk of perforation compared with conventional dilation and curettage.[15] The TruClear™ morcellator employs a blade inserted through a hysteroscope to simultaneously cut and aspirate tissue because it has a mechanical design, and there is no risk of energy-induced scarring of the uterus. It is specifically indicated to remove polyps, Type 0 and Type 1 submucosal fibroids. Unlike the other treatment options utilising electro-surgery with glycine as the fluid medium, these procedures have limitations because of the risk of hyponatraemia from absorption of glycine, potential cervical trauma due to the requirement of cervical dilators, and difficulties in managing the intrauterine chips from resected pathology. Bipolar techniques to vapourise tissue using small instruments and normal saline are used to overcome some of these issues, but the sample for histopathology may not be obtained with these techniques.

The rationale of this investigation was to assess the results experienced by patients who underwent hysteroscopy using the TruClear™ hysteroscope, focusing on the efficacy of pathology removal, amelioration of symptoms, and the incidence of complications. The objective of this study was to find out the outcomes of patients who underwent hysteroscopy using TruClear™ hysteroscope in terms of removal of pathology, improvements in symptoms and postoperative complications.

METHODOLOGY

This retrospective study was conducted at the Gynaecology and Obstetrics Department of Shifa International Hospital, Islamabad, Pakistan, after obtaining approval from the Institutional Review Board and Ethical Committee (Reference Number: 0141-22, Dated: 28th May 2022). All female patients aged 18 and above who underwent the removal of endometrial polyps and submucous fibroids using TruClear™ hysteroscopic tissue removal system were included in the study. Pregnant patients and those with a history of cardiac failure, chronic renal failure, and bleeding diathesis were excluded from the study. Due to the retrospective nature of the study, informed consent from the patients was not required.

After collecting baseline information from patients, presenting complaints and gynaecological and obstetric history were recorded. Electronic and paper-based data were used to note the pathologies' number, size, and location. Data about the complete removal of pathology (endometrial polyps and submucosal fibroids), mean operating time, and postoperative complications such as bleeding and perforation were extracted from operative notes and patient charts. Patients' charts were scanned to note the resolution of symptoms and any required co-intervention. Any recurrence was also reported. Recall bias was eliminated by using patient follow-up visit charts and notes to record the presence / absence of outcomes. The follow-up was set up to 6 months after the procedure.

Statistical analyses were performed with Statistical Package for Social Sciences (SPSS, version 21.0, Statistics, Chicago, IBM, USA). Mean and standard deviation or median with IQR were reported for quantitative variables such as age and operative time and analysed by ANOVA and Kruskal-Wallis test among the groups. The normality of data was assessed by the Shapiro-Wilk's test. Frequency and percentage were computed for qualitative variables such as parity, miscarriage, symptoms, intraoperative bleeding, resolution of symptoms, other interventions required, and recurrence and analysed by Chi-square test or Fisher's exact test among groups and operative time. A $p \leq 0.05$ was considered significant.

RESULTS

A total of 45 women undergoing hysteroscopic tissue removal with the TruClear™ hysteroscope were included in this study. The average age of the patients was 35.2 ± 7.46 years. Almost 62% of the women were multiparous (parity 2-5) and 40% (18/45) had a history of miscarriages. Interestingly, patients with submucosal fibroids were older with a mean age of 38.7 years, whereas those with polyps were younger with a mean age of 34.1 years. Patients with malignancy were even younger, with a mean age of 33.5 years. Heavy menstrual bleeding (HMB) was the most prevalent symptom seen in 73.3% of cases, followed by irregular vaginal bleeding (IVB) in 11.1% of cases as shown in Table I. ANOVA was used for mean difference and the Chi-square / Fisher's exact test for proportion difference; however, no demographic variable was found to be statistically significant for a poor outcome.

The most frequent lesion was a polyp in 21 (47%) instances, followed by submucosal fibroid in 12 (27%) cases, mixed pathology in 10 (22%) cases, and malignancy in 2 cases (4%). A single fibroid was found in 29% (13/45) women, whereas 15.5% (7/45) had multiple fibroids. Similarly, almost 58% (26/45) women had a single polyp and 13% (6/45) had multiple polyps. Other interventions were required in 10 patients (22.2%).

The outcomes of the study are given in Table III. The overall mean operative time was 36.46 ± 24.94 minutes with a range of 14-120 minutes. This was higher for patients with mixed pathology (35 minutes) compared to those with polyps (27 minutes) or submucosal fibroids (32 minutes); however, this value was not statistically significant when Kruskal-Wallis test was applied.

Complete removal was achieved in all cases. Most patients (68.9%) reported complete improvement in symptoms, the most marked improvement was seen in patients with polyps (76.2%) followed by fibroids (66%) and mixed pathology (60%), however, this was not found to be statistically significant. Persistent symptoms were reported in 31% of women after the procedure.

Table I: Demographic information.

Variables	Overall n = 45	Polyp n = 21	Submucosal fibroid n=12	Mixed pathology n = 10	Other malignancy n = 2	p-value
Age (years) †	35.62 ± 7.46	34.10 ± 8.28	38.67 ± 6.91	35.60 ± 6.50	33.50 ± 2.12	0.397
Parity						0.346
Nulliparous (0)	8 (17.8%)	4 (19%)	2 (16.7%)	2 (20%)	0 (0%)	
Primiparous (1)	5 (11.1%)	1 (4.8%)	1 (8.3%)	1 (10%)	2 (11.1%)	
Multiparous (2-5)	28 (62.2%)	14 (66.7%)	8 (66.7%)	6 (60%)	0 (0%)	
Grand multiparous (6)	4 (8.9%)	2 (9.5%)	1 (8.3%)	1 (10%)	0 (0%)	
Miscarriage	18 (40%)	8 (38.1%)	4 (33.3%)	5 (50%)	1 (50%)	0.860
1	11 (24.4%)	5 (23.8%)	2 (16.7%)	3 (30%)	1 (50%)	
2	4 (8.9%)	1 (4.8%)	1 (8.3%)	2 (20%)	0	
3-5	3 (6.6%)	2 (9.5%)	1 (8.3%)	0	0	
Symptoms						
HMB	33 (73.3%)	17 (81%)	9 (75%)	6 (60%)	1 (50%)	0.551
IMB	3 (6.7%)	1 (4.8%)	1 (8.3%)	1 (10%)	0	0.919
IVB	5 (11.1%)	1 (4.8%)	1 (8.3%)	3 (30%)	0	0.186
Subfertility	2 (4.4%)	0	1 (8.3%)	0	1 (50%)	0.009
HMB + Subfertility	1 (2.2%)	1 (4.8%)	0	0	0	0.760
IMB + Subfertility	1 (2.2%)	1 (4.8%)	0	0	0	0.760

HMB = Heavy menstrual bleeding, IVB = Irregular vaginal bleeding, IMB = Intermenstrual bleeding, NA = Not applicable. ANOVA test was applied for mean difference† and Chi-square or Fisher's exact test for proportion difference.

Table II: Comparison of parameter and outcome with operative time.

Variables		Operative time (minutes)				p-value
		< = 30		>30		
		Count	%	Count	%	
Ultrasound finding	Polyp	13	59.1%	5	33.3%	0.297
	SM fibroid	5	22.7%	5	33.3%	
	Mixed path	4	18.2%	5	33.3%	
Parity	Nulliparous (0)	1	4.5%	7	41.2%	0.016
	Primiparous (1)	1	4.5%	2	11.8%	
	Multiparous (2-5)	18	81.8%	6	35.3%	
	Grand multiparous (6)	2	9.1%	2	11.8%	
Miscarriage	0	11	50.0%	13	76.5%	0.277
	1	8	36.4%	3	17.6%	
	2	2	9.1%	0	0.0%	
	3-5	1	4.5%	1	5.9%	
Fibroid number	0	14	63.6%	8	47.1%	0.221
	1	4	18.2%	8	47.1%	
	2	3	13.6%	1	5.9%	
	3-6	1	4.5%	0	0.0%	
Polyp number	0	5	22.7%	6	35.3%	0.178
	1	13	59.1%	10	58.8%	
	2	4	18.2%	0	0.0%	
	>2	0	0.0%	1	5.9%	
Complications	Bleeding	1	4.5%	0	0.0%	0.373
Removal of lesion	Complete	22	100.0%	17	100.0%	NA
Resolution of symptoms?	No	6	27.3%	6	35.3%	0.59
	Yes	16	72.7%	11	64.7%	
Any other interventions required?	No	17	77.3%	14	82.4%	0.697
	Yes	5	22.7%	3	17.6%	
Recurrence?	No	19	86.4%	17	100.0%	0.243
	Yes	3	13.6%	0	0.0%	

Chi-square or Fisher's exact test.

Table III: Comparison of outcome of TruClear™ hysteroscopy in patients with submucosal fibroids and endometrial polyps (n = 43).

Outcome	Overall n = 43	Polyp n = 21	Submucosal fibroid n = 12	Mixed path n = 10	p-value
Operative time (Min) †	36.46 ± 24.94	27.50	32.5	35	0.307
Median [25th - 75th percentile]	[14 - 120]	[18.75 - 33.25]	[20.75 - 41.25]	[27 - 46]	
Removal of lesion‡					
Complete	45 (100%)	21 (100%)	12 (100%)	10 (100%)	NA
Partial		0	0	0	
Intraoperative bleeding‡	1 (2.3%)	1 (4.8%)	0	0	0.585
Resolution of symptoms ‡					0.632
Yes	31 (68.9%)	16 (76.2%)	8 (66.7%)	6 (60%)	
No	14 (31.1%)	5 (23.8%)	4 (33.3%)	4 (40%)	
Other interventions required‡	10 (22.2%)	2 (9.5%)	5 (41.7%)	3 (30%)	0.093
Recurrence‡	4 (8.9%)	1 (4.8%)	0	3 (30)	0.003

Results are presented as median [25-75 percentile] and n (%). Kruskal-Wallis test† Chi-square or Fisher's exact test‡.

However, most of them did not require any intervention and the symptoms subsided on their own. Additional interventions were required in 22% of women, such as an intrauterine hormonal device which was inserted in 13.3% of the patients. One patient (2.2%) was also managed with a myomectomy. Two patients were diagnosed with malignancy which was revealed in the postoperative pathology report. These patients underwent an additional procedure of total laparoscopic hysterectomy and bilateral salpingo-oophorectomy with lymph node dissection. Submucosal fibroids showed a higher risk of requiring an additional intervention with 41.7% of patients, requiring some form of post-procedure management. Mixed pathology had a lower risk of additional interventions (30%) whereas polyps carried the least risk of the post-procedure intervention (9.5%). This risk was, however, not found to be statistically significant (p = 0.093).

The main outcomes are mentioned in Table II. The main complication of bleeding was observed in only one patient (2.2%) and was managed by intraoperative intrauterine balloon insertion. The overall recurrence rate was 8.9% (4/45) as shown in Table II. Submucosal fibroid showed no recurrence, however, polyps showed a recurrence rate of 4.8%. The recurrence rate was significantly higher in patients with mixed pathology with almost 30% of patients experiencing a recurrence (p = 0.003). Baseline demographics and outcomes were compared to operative time. A cut-off of 30 minutes was taken for operative time. No demographic variable was found to be significant for reduced or prolonged operative time except the parity. Null parity was found to be associated with a higher operative time whereas most multiparous women (81.8) had a lower operative time. Operative time did not have a significant impact on the main outcomes of bleeding, recurrence, or use of additional interventions.

DISCUSSION

Many studies have compared the removal of intrauterine pathologies using tissue removal systems. A meta-analysis comparing tissue removal systems to conventional resectoscopes by Yin *et al*.[16] showed that the mean operating time differed significantly for polypectomy, performed by hysteroscopic tissue removal systems, compared to conventional resectoscopes (p <0.0001).[16] A mean reduction time of 2.93 minutes was observed for hysteroscopic removal systems. Similarly, a higher success rate was seen for patients treated with a hysteroscopic removal system (95.5%) than with conventional resectoscopy (86.3%).[16] The present study did not have a control group for comparison but the removal of pathology was much higher at 100%. Their study was based on the pooled data of 498 patients whereas the sample size of the present study was limited.

A prospective multicentred trial was done by Scheiber *et al*. where 187 fibroids and 372 polyps were removed from 278 subjects.[17] They also found similar results; they reported a complete pathology removal of 99.3% for polyps and 86.8% for fibroids. Adverse events reported by them included four incidents of blunt cervical trauma and a single postoperative case of pedal oedema, no such adverse events were reported in the present study.

AlHilli *et al*. showed a very low complication and recurrence rate of polyps when treated with intrauterine morcellation systems.[18] This finding is reflected in the present study as well, however, polyps were found to have a greater recurrence rate than submucosal fibroids. Hamerlynck *et al*. performed a retrospective study on 315 women undergoing hysteroscopic morcellation for uterine pathologies.[19] They concluded that the morcellator can only be used for the complete removal of Type 0 and 1 myomas. In three cases, conversion to resectoscopy was necessary; however, no such instance was reported in the present study. They reported no complications in all their patients whereas this study had a single instance of bleeding.

Yong *et al*. performed a similar procedure but with the use of a MyoSure tissue removal system and found the operative time to be considerably lower when compared to this study (19.3 *vs*. 27.5 minutes).[20] The intraoperative blood loss ranged from 2 to 50 ml with an average blood loss of 10.8 ml, however, the amount of blood loss was not a measured outcome in the present study.

Luerti *et al*. showed in their study that the procedure was safe, with a 90% (n = 357) success rate without complications,[21] which was lower than this study, however, the sample size of this study was much lower as well. Incomplete removal of the endometrial polyps was documented in 39 patients, however, no incomplete removal of endometrial polyps was documented in the present study.

Rovira Pampalona *et al.* compared TruClear™ system with electrosurgical resection and found the average operating time (8.3 min *vs*. 12.0 min, p = 0.014), insertion time (5.0 *vs.* 9.0 minutes, p <0.001), and the number of insertions (1.0 *vs.* 8.2, p <0.001) were significantly lower in the morcellation arm than in the electrosurgical resection arm.[22] Similarly, Tsuchiya *et al.* compared TruClear™ with the Versapoint system and found that there was a 91% success rate with the TruClear System™ compared to a 69% success rate with the Versapoint® system, showing a clear advantage of the TruClear™ tissue removal system.[23]

The strength of this study is that this is the first-ever report of the outcomes of the TruClear™ hysteroscope in Pakistan which is a state-of-the-art tissue removal system. It is a detailed, although limited, report of this novel technique.

The limitations of the study and its small sample size andretrospective nature, which are insufficient to establish causality.

CONCLUSION

TruClear™ hysteroscopic tissue removal system is a safe and effective method to manage intrauterine pathologies and leads to improved patient outcomes and fewer complications. Future studies can include a control group for comparison and recruit a larger cohort to test the hypothesis more effectively.

ETHICAL APPROVAL:
The research was done after obtaining approval from the Institutional Review Board and Ethical Committee (Reference number: 0141-22, Dated: 28th May 2022).

PATIENTS' CONSENT:
Informed consent was not required due to the retrospective nature of the study.

COMPETING INTEREST:
The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:
SF: Conceptualising, supervision, validation, and resources.
MT: Data curation, investigation, visualisation, methodology, and project administration.
TZ: Formal analysis, software, writing original draft, manuscript writing, review, and editing.
All authors approved the final version of the manuscript to be published.

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