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Original Article

# A "See and Treat" Office Procedure for Retained Products of Conception Removal After Normal Vaginal Delivery Using Manual Vacuum Aspiration: Preliminary Efficacy and Reproductive Outcomes

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**ABSTRACT** **Study Objective:** To compare the efficacy and reproductive outcomes of an ultrasound-guided manual vacuum aspiration (MVA) procedure with the widely accepted operative hysteroscopic (OH) procedure in the removal of retained products of conception (RPOCs) after normal vaginal delivery.

**Design:** A retrospective cohort study (Canadian Task Force classification II-2).

**Setting:** A university-affiliated tertiary medical center.

**Patients:** Eighty-six patients after normal vaginal delivery diagnosed with RPOCs from 2005 through 2015. This study was approved by the local institutional review board.

**Interventions:** Treatment with either MVA or OH for patients diagnosed with RPOCs.

**Measurements and Main Results:** Of 86 patients, 23 underwent remnant removal by ultrasound-guided MVA using a 6- to 7-mm catheter in a "see and treat" office procedure. Sixty-three patients underwent remnant removal using the OH procedure. Follow-up included sonographic examination 3 to 5 weeks after the procedure and long-term follow-up on complications and reproductive outcomes. Successful remnant evacuation and the overall complications rates were similar when comparing the MVA group and the OH group (95.7% vs 96.8% and 4.3% vs 4.7%, respectively). Conception rates and miscarriage rates were comparable in the MVA and OH groups (78.6% vs 72.2% and 9.1% vs 14.8%, respectively).

**Conclusion:** Preliminary results from 23 patients suggest that MVA is an efficient procedure with low complication rates and satisfactory reproductive outcomes. It does not require anesthesia or operating room facilities, allowing an immediate and inexpensive "see and treat" option for RPOCs. Further larger controlled trials are required. Journal of Minimally Invasive Gynecology (2017) 24, 1007–1013 © 2017 AAGL. All rights reserved.

*Keywords:* Hysteroscopy; Intrauterine adhesions; Manual vacuum aspiration; Retained products of conception; Transvaginal ultrasound

Retained products of conception (RPOC) are common complications after abortion or delivery. Diagnosis is challenging. Possible criteria for a standard definition include the time interval from abortion or delivery to observation; clinical signs such as fever, abnormal vaginal bleeding, or abdominal pain; and sonographic features of an intrauterine solid or heterogeneous tissue with or without blood flow and measurements of endometrial thickness [1–5]. The incidence of RPOCs after delivery varies and is affected by placental pathologies such as placenta accreta, the need for manual removal of the placenta after delivery, and the diagnostic criteria of a retained placenta. Postpartum RPOCs may cause short-term complications such as massive vaginal bleeding or endometritis. They are also associated with the development of intrauterine adhesions (IUAs), secondary infertility, recurrent abortions, and other placental pathologies [6] as a result of a traumatic intervention to the sensitive endometrium in the hypoestrogenic puerperal period.

The management of women suspected of having a postpartum RPOC is challenging because of the lack of a clear evidence-based definition and guidelines. The traditional surgical treatment of postpartum RPOCs until 2 decades

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ago was dilatation and curettage (D&C). In 1997, Goldenberg et al [7] reported the use of operative hysteroscopy (OH) for the treatment of RPOCs. Consequently, additional studies have been performed, and reports of increasing experience with the OH technique were published [8,9]. The outcomes of hysteroscopy treatment include low complication and IUA rates and high rates of subsequent pregnancies [10]. Nevertheless, this procedure is performed under general anesthesia and therefore requires operating room facilities and staff.

Electric vacuum aspiration was originally developed in the mid-20th century as a method for abortion. Manual vacuum aspiration (MVA) is a nonelectrically generated alternative suction source for vacuum aspiration originally developed in 1973 by the International Pregnancy Advisory Services and intended for countries where electricity was often unavailable. MVA has been in widespread use for more than 30 years for the management of incomplete abortions, the termination of early pregnancies, and endometrial sampling. The MVA procedure is a hand-operated office procedure. It includes the use of a plastic flexible catheter connected to a 60-mL syringe for vacuum aspiration. The manual vacuum aspirator is portable and inexpensive. Several large case series reported low failure and complication rates with the MVA procedure when used for elective abortions [11–13]. In this study, we describe our modified technique using our experience in ultrasound (US)-guided MVA in order to extract postpartum RPOCs in a short, simple, "see and treat" office procedure and compare preliminary results regarding safety, efficacy, and reproductive outcomes of this procedure with the widely accepted OH procedure.

## Materials and Methods

This retrospective cohort study included women after normal vaginal delivery at term (>37 weeks) diagnosed with suspected RPOCs by either sonography or diagnostic hysteroscopy and treated by either MVA or OH between 2005 and 2015.

The cutoff diameter for which evacuation was needed was 15 mm. The material extracted during the procedure was later confirmed as an RPOC by a histologic examination. Diagnosis by US was performed during a routine follow-up at the end of the puerperium (6 weeks) or indicated by symptoms of abdominal contractions or recurrent vaginal bleeding. Further evaluation included sonographic examination including Doppler or diagnostic hysteroscopy. The RPOC was examined, and its size was measured. Exclusion criteria were multiple gestations, delivery by cesarean section, premature delivery, placental pathology, previous diagnosis of additional endometrial or uterine abnormalities, and a finding other than an RPOC on histologic examination.

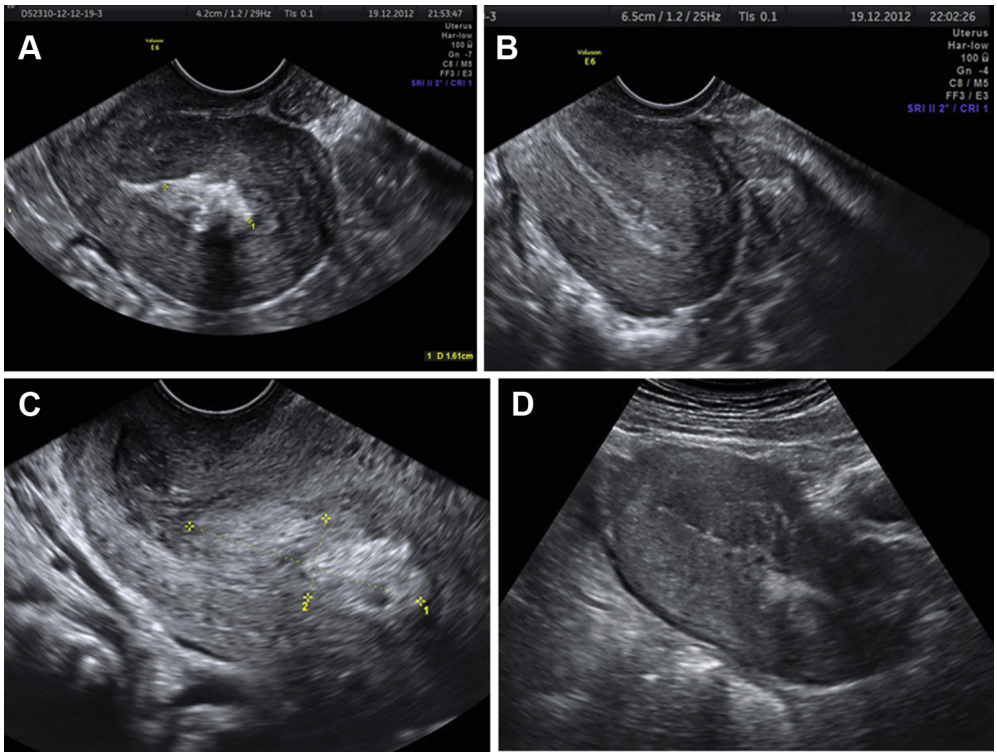
Patients in the study group were evaluated by transvaginal US and treated by a single US specialist (N.Y). They underwent removal of the RPOC by MVA using a 6- or 7-mm catheter. All patients in this group underwent transvaginal US using a Voluson GE E6 system device and IC 5-9 MHz transvaginal probe (GE Healthcare, Milwaukee, WI). The uterine cavity was scanned for endometrial regularity, thickness, and abnormal findings. A suspected retained placenta was scanned by 2-dimensional ultrasound and Doppler in order to estimate the location, size, and vascularity of the retained tissue. After diagnosis, each patient then received a full explanation regarding the possible treatment options including operative hysteroscopy, MVA, and expectant management. OH was presented as the standard approach for RPOC management performed under general anesthesia. Further explanation was a description of the MVA with an additional explanation that MVA is an experimental office procedure for RPOC removal after normal vaginal delivery that offers an immediate removal of the RPOC with no need for anesthesia or preoperative assessment. Management by either MVA or OH was decided according to the patients' preference. Women who chose to undergo MVA had the procedure immediately at the same office setting. The MVA procedure was performed under sonographic guidance by the MVA operator. A vaginal speculum was inserted, and the vagina was prepared using water-based povidone- iodine. Using abdominal ultrasound guidance, a 6- or 7-mm width catheter was inserted transcervically into the uterine cavity. No dilatation was needed in any of the cases. The catheter was connected to a 60-mL syringe, and the tissue was aspirated until a clear endometrial cavity was shown (Fig. 1A–D). Abdominal US guidance was performed throughout the entire procedure. No pain reliever or local anesthesia was required. A macroscopic inspection confirmed the diagnosis of a placenta tissue remnant, and it was later sent for histologic examination, which confirmed the diagnosis. Preventive antibiotic treatment with amoxicillin-clavulanate (Augmentin; SmithKline, Beecham Pharmaceuticals, Worthing, UK) was given for 1 day (1 gram twice a day, 2 doses overall), and the patient left the office immediately at the end of the procedure. Follow-up was performed 3 to 5 weeks after the procedure with transvaginal US.

Women in the control group underwent removal of the RPOC in an operative hysteroscopy under general anesthesia. At the beginning of surgery, patients received a single dose of 1-2 grams prophylactic first-generation cephalosporin (Cefamezine; Panpharma, Fougeres, France). The operative hysteroscopic procedure was performed using a Gynecare Versapoint bipolar system (Ethicon, Inc, Somerville, NJ) with normal saline solution for uterine distention and constant observation for fluid in-out balance. Our institution protocol instructions include preparation for the termination of the procedure when reaching a fluid deficit estimation of 2 L or more to prevent fluid overload. In all cases, a loop electrode was used for the removal of the RPOC.

A complication was defined as termination of the procedure before complete evacuation of the remnant with a need for further intervention, abnormal bleeding resulting in blood transfusion, abnormal pelvic pain (resulting in longer than standard hospital stay or readmission within a week after the procedure for at least 24 hours), or perforation to the

**Fig. 1**

Transvaginal ultrasound visualization of retained products of conception in 2 patients 5 to 6 weeks after normal vaginal delivery (**A** and **C**) before and (**B** and **D**) after manual vacuum aspiration showing a successful, complete evacuation of the retained products of conception in both cases.




uterine fundus or damage to the adjacent organs. Follow-up for all patients included sonographic examination 3 to 5 weeks after the procedure and a physical examination and data collection from electronic and hard copy records at least 12 months after the procedure. Data collection included demographic information and general and gynecologic background. The primary outcomes were procedure efficacy (defined as complete evacuation of the RPOC) and future conception and miscarriage rates. The study was not powered to identify the complication rate, which is rather low and requires a much large number of patients in each study arm according to power calculation. The secondary outcomes included the time interval from birth to diagnosis and from diagnosis to treatment, the size of the RPOC (largest diameter in millimeters), the presence of blood flow to the finding, the width of the catheter or Hegar used in the procedure, the length of the procedure, and hospitalization after the procedure. In the majority of cases in the MVA and OH groups, data regarding consequent pregnancies and births were available.

This study was approved by the Human Investigation Review Board of Hadassah Hebrew University Medical center (institutional review board approval number: HMO-0661-15).

### *Statistics*

Categoric data were analyzed using the chi-square or Fisher exact test. Continuous data are presented as the mean ± standard deviation and calculated using the Student *t* test. SPSS 19 (for Windows software) was used for statistical analysis and the calculation of odds ratios and confidence intervals. A p value $<.05$ was considered statistically significant.

## Results

Ninety-one women were diagnosed with RPOCs and treated by either MVA or OH between January 2005 and December 2015. Eight women were excluded from this study; 5 of them delivered by cesarean section, and 3 women were previously diagnosed with uterine anatomic abnormality. Eighty-six women were included in this cohort study after applying the exclusion criteria. Basic characteristics, gynecologic features, and obstetric background did not significantly differ between the groups (Table 1). The study group (MVA) included 23 patients aged 23 to 39 years (mean = 29.6 ± 5.5 years) who have had normal vaginal delivery at term. All women in this group addressed our clinic for evaluation 3 to 12 weeks (mean = 5.9 ± 1.0 weeks) after birth. Sixteen of them (78.3%) presented with abnormal, prolonged, or increased vaginal bleeding. Five patients (21.7%) arrived for a routine follow-up visit at the end of the puerperium without presenting symptoms or complaints. Patients in this group underwent transvaginal sonography, and in all cases in this group the MVA procedure was performed immediately at diagnosis. The control group (OH)

**Table 1**

Basic characteristics of the operative hysteroscopy (OH) and manual vacuum aspiration (MVA) groups

| Parameter | MVA (n = 23) | OH (n = 63) | OR (95% CI) | p value* |
|---|---|---|---|---|
| Age (years) | 29.96 ± 5.22 | 31.73 ± 5.99 | NA | .14 |
| Primipara | 7 (30.4) | 24 (38.1) | 0.71 (0.26–1.98) | .51 |
| Multipara | 16 (69.6) | 39 (61.9) | 0.71 (0.26–1.98) | .51 |
| Symptoms at diagnosis† | 18 (78.3) | 49 (77.8) | 1.03 (0.32–3.27) | .96 |
| Days from diagnosis to procedure | 0 | 17.48 ± 14.95 | NA | <.001 |
| Days from birth to diagnosis | 41.84 ± 6.88 | 47.41 ± 26.63 | NA | .09 |
| Remnant size (largest diameter) (mm) | 23.83 ± 9.41 | 22.15 ± 10.47 | NA | .36 |
| Blood flow to the placental remnant‡ | 17 (73.9) | 36 (57.1) | 2.12 (0.74–6.11) | .16 |

CI = confidence interval; MVA = manual vacuum aspiration; NA = not applicable; OH = operative hysteroscopy

Data are given as mean ± standard deviation or n (%).

* The Student *t* test for independent samples and the Fisher exact test or Pearson chi-square test as appropriate.

† Symptoms were defined as abnormal vaginal bleeding, fever, and pelvic pain or tenderness.

‡ Demonstrated by ultrasound Doppler.

consisted of 63 patients aged 19 to 45 years (mean = 31.7.0 ± 6.0 years) who underwent OH for postpartum RPOC removal. In this group, 49 patients (77.8%) were symptomatic, and a diagnosis was made after sonographic examination followed by a diagnostic hysteroscopy in some of the cases.

The mean follow-up time was 30.91 ± 20.87 months in the MVA group and 48.61 ± 30.86 months in the OH group. Three patients in the MVA group and 14 patients in the OH group were lost to follow-up. Fourteen of 20 patients in the MVA group and 36 of 49 patients in the OH group were categorized as patients with "desire to conceive" (6 patients in the MVA group and 13 patients in the OH group were under oral contraceptive treatment or after intrauterine device insertion). The time interval between diagnosis and RPOC removal by OH was 1 to 56 days (mean = 17.5 ± 15.0 days). All patients underwent OH under general anesthesia in a tertiary medical center. The mean size of the RPOC and the presence of blood flow to the placental remnant did not differ (Table 2). The duration of the procedure was significantly shorter in the MVA group (5.0 ± 1.8 vs 21.5 ± 10.3 minutes, $p < .05$).

Complications occurred in 3 of 63 cases in the OH group and in 1 case in the MVA group. In the OH group, 1 procedure was terminated without complete removal of the remnant because of fluid overload (over 2 L) with a consecutive successful OH treatment 4 weeks later. One woman was readmitted 6 hours from discharge for 28 hours because of abdominal pain that resolved spontaneously. Another woman in this group was diagnosed with intrauterine

**Table 2**

A comparison of procedure outcomes: operative hysteroscopy versus manual vacuum aspiration

| Parameter | MVA (n = 23) | OH (n = 63) | OR (95% CI) | p value* |
|---|---|---|---|---|
| Catheter width (mm) | 6.52 ± 0.50 | 7.98 ± 1.25 | NA | <.001 |
| Duration of procedure (min) | 5.04 ± 1.79 | 21.51 ± 10.29 | NA | <.001 |
| Complete evacuation | 22 (95.7) | 61 (96.8) | 1.38 (0.12–16.05) | .79 |
| Overall complications | 1 (4.3) | 3 (4.7) | 0.91 (0.09–9.21) | .94 |
| Intraoperative† | 0 | 1 (1.6) | 0.89 (0.04–22.54) | .94 |
| Postoperative‡ | 1 (4.3) | 2 (3.2) | 1.39 (0.12–16.06) | .79 |
| Conception rate§ | 11/14 (78.6) | 26/36 (72.2) | 0.71 (0.16–3.09) | .65 |
| Miscarriage rate | 1/11 (9.1) | 4/26 (14.8) | 0.55 (0.05–5.56) | .61 |

CI = confidence interval; MVA = manual vacuum aspiration; NA = not applicable; OH = operative hysteroscopy

Data are given as mean ± standard deviation or n (%) or n/N (%).

* The Student *t* test for independent samples and the Fisher exact test or Pearson chi-square test as appropriate.

† An intraoperative complication was defined as a premature termination or failure of the procedure with a need for further intervention (because of technical difficulty, fluid imbalance, excessive bleeding, or perforation of the uterus).

‡ A postoperative complication was defined as fever (>38) pain or bleeding resulting in either hospital stay or readmission within a week after the procedure for at least 24 hours or a subsequent diagnosis of intrauterine adhesions.

§ Within 6 months among women with a desire to conceive and no current use of contraception.

adhesions during evaluation of secondary infertility 16 months after the OH and eventually underwent successful resective hysteroscopic treatment. In the MVA group, 1 woman was referred to an OH because of an asymptomatic 5 × 9 mm remnant diagnosed 4 weeks after the MVA procedure. Among patients available for long-term follow-up with a desire to conceive (36 women in the OH group and 14 women in the MVA group), similar conception and miscarriage rates were observed in both groups.

Separate analysis was performed comparing the entire MVA group (23 patients) with a modified OH group including only patients who underwent RPOC removal after less than 90 days from birth (50 patients). This analysis showed similar results to the comparison between the MVA group and the entire OH group. Basic characteristics, such as age, presenting symptoms, remnant size, and the time interval from birth to diagnosis and from diagnosis to procedure, did not differ between the groups. Procedure outcomes in the OH subgroup such as duration of the procedure, complication rate, and reproductive outcomes were similar to those of the entire OH group.

Additional subset analyses included comparison between the groups of patients with remnant size between 15 and 30 mm, patients with a positive Doppler study, and symptomatic patients separately. These analyses showed similar results to the primary comparison regarding the length of the procedure, the time from birth to diagnosis, and the decision on active management and reproduction outcomes.

## Discussion

In this cohort study, we present preliminary results of an US-guided office procedure for the removal of RPOCs after normal vaginal delivery using MVA. Indeed, the major limitations of our study are the small size of the study group (23 patients) and its retrospective design, limiting the ability to conclude wider and more significant implications, especially regarding complications such as uterine trauma. However, to the best of our knowledge, this is the first study to present and evaluate the MVA technique for RPOC removal after normal vaginal delivery, and reporting this method details and preliminary results is of importance and can perhaps encourage evaluation of this inexpensive applicable "see and treat" technique in further, larger trials.

A standard definition for RPOC is not yet well established. Although some protocols have been proposed, uncertainty still remains, resulting from the overlap between the sonographic appearance of the postpartum or postabortal uterine cavity, the lack of consensus regarding the appropriate endometrial thickness cutoff, and modification in sensitivity in sonographic diagnosis including Doppler along the puerperium [5,14,15].

Hysteroscopy allows direct visualization of the uterine cavity and is considered the standard of choice to diagnose uterine pathologies. However, transvaginal US is a widely used and accurate examination option for evaluation of the uterus. Several studies have shown conflicting data regarding the diagnostic accuracy of transvaginal US compared with hysteroscopy in the evaluation of abnormal uterine bleeding and the demonstration of myomas or polyps [16–18]. Nevertheless, when examining the sensitivity and specificity of both methods in the diagnosis of RPOCs, the use of transvaginal US yielded comparable and partially favorable results over the hysteroscopic procedure [19]. Questions still remain regarding whether routine transvaginal US is warranted in all patients after abortion or normal delivery and what is the ideal time interval from abortion or delivery to routine US [20,21]. Regardless, the current common standard of practice does not include early US screening in uncomplicated asymptomatic cases. The MVA procedure is in wide use for early pregnancy termination and is considered a safe and simple method with an extremely low complication rate [22].

A systematic review compared MVA with electronic vacuum aspiration for the termination of first trimester pregnancies and showed similar complete abortion rates [23]. A Cochrane review [22] compared the safety and efficacy of MVA versus D&C and found no statistically significant differences in numerous intraoperative and postoperative factors including febrile morbidity, incomplete or need for repeat uterine evacuation procedures, and postoperative abdominal pain. Moreover, a large randomized controlled trial evaluated the MVA procedure compared with D&C and found significantly lower intraoperative blood loss with the MVA procedure, whereas postabortal sepsis and re-evacuation rates were similar [24]. We found no report of MVA use for RPOCs after term delivery in our literature review.

Our data additionally show an expected obvious difference in the time interval from diagnosis to definitive treatment between the 2 groups. Women in the OH group underwent hysteroscopy after an average of more than 17 days after the diagnosis compared with the MVA group in which definitive treatment was performed immediately at diagnosis. This difference is a result of the ability to perform the MVA as a "see and treat" office procedure with no need for preoperative assessment, general or regional anesthesia, or operating room facilities. Although some studies showed no correlation between the time interval from diagnosis to treatment and the rate of IUAs [25], other studies showed that the time lag from diagnosis to treatment correlates with the adherence of RPOCs to the uterine walls and subsequent IUA development [26]. Therefore, MVA can be considered as a preferred solution for RPOC removal in elected cases because of these advantages.

The overall complication rates in the OH group in our study were relatively low and similar to those mentioned in previous studies [27]. A recent systematic review [28] examined the long-term complications (eg, IUA) and reproductive outcomes after the removal of RPOCs by either sharp curettage or OH. This review showed rather high rates of IUA in both methods (up to 30% vs 13%,

respectively). Incomplete evacuation was also reported in high rates after sharp curettage (29%) compared with OH (1%); however, reproductive outcomes were similar although there was a tendency toward earlier conception after OH. Our study also showed similar results to those of the aforementioned review regarding consecutive pregnancy rates in women desiring to conceive in both groups with no significant difference between the groups in this parameter or miscarriage rates. Although office hysteroscopy has been previously described as a valid option for the management of small placental remnants [29], limited data exist regarding the efficacy and reproductive outcome of this method, and no controlled or prospective studies have been performed.

An additional potential limitation is a selection bias in the allocation of prolonged and more complicated cases to the OH group rather than cases that might have resolved spontaneously because of the fact that OH is considered the preferred and verified treatment option. We addressed this issue by performing additional analyses comparing the MVA group with an OH subgroup that included only patients with a maximal time interval of 75 days from delivery to RPOC removal. The results were similar to the extended OH group results, including the length of the procedure, complications and hospitalization rates, and reproductive outcomes. Moreover, we found no significant difference between the entire OH group and the MVA group regarding the time interval from birth to diagnosis and the decision on the active management approach (data available upon request).

An important parameter to consider when comparing these 2 techniques is the major difference in facilities and equipment required for the procedure determining the cost of each procedure. Both operative hysteroscopy and the ultrasound-guided MVA require a skilled operator. However, although the cost of an OH procedure includes the hysteroscopy equipment, sterilization costs, and the operating room and staff expenses, the MVA procedure requires a disposable catheter kit alone, thus making this office procedure much more available and cheaper than the OH procedure.

In conclusion, based on our preliminary results, the sonography-guided MVA procedure for the removal of RPOCs is a safe and efficient procedure with satisfactory reproductive outcomes and should be further evaluated by larger randomized controlled trials in order to confirm our findings and support a more prevalent use of this method.

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