Comparison of manual vacuum aspiration to traditional methods of managing early pregnancy miscarriage

How does MVA compare to alternative methods of miscarriage management?

Oscar MacCormac 1,2*, Alexandra Edwards 3, Murray Forsyth 1, Fanny Ti 1 and Shilpa Deb 1

Abstract: A prospective study of 125 patients diagnosed with first trimester miscarriage was carried out in order to compare management outcomes and patient satisfaction. Miscarriage managed medically and surgically was compared. A comfort score between 1 and 5 (1 very uncomfortable, 5 no discomfort) was given by each patient during, where appropriate, and following the intervention; rates of success (determined by negative scan/absence of re-presentation) and whether the patient required subsequent admission to hospital/delayed stay (deemed as >24 h) were also recorded. Manual vacuum aspiration (MVA) compared favourably vs other procedures with a mean comfort score during procedure of 2.61 vs 3.9 in medical management and a mean comfort score post procedure of 3.95 vs 4.0 for MMM and 3.81 for surgical management. Similarly, MVA demonstrated a lower failure rate (2.5%) vs MMM (68%) and SMM (10%) and none required admission or a delayed stay vs MMM (4%) and SMM (10%).

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ABOUT THE AUTHOR

Oscar MacCormac has completed foundation training in the UK, during which he worked as part of the obstetrics and gynaecology team; it was here he met Shilpa Deb, consultant gynaecologist, who had begun offering MVA. From this, the below study was formed, with Alexandra Edwards (special interest in community sexual and reproductive health) Murray Forsyth (a plastic surgery enthusiast at present with a specific interest in labial reconstructive surgery) and Fanny Ti, another colleague in the department of obstetrics and gynaecology with an interest in pursuing a career in this specialty. Together, this group aim to offer MVA as an effective treatment for first trimester miscarriage more widely to the UK population.

PUBLIC INTEREST STATEMENT

Manual vacuum aspiration (MVA) is a management option for first trimester miscarriage that has been offered on a limited basis within the UK. This study aims to assess its efficacy within the context of a UK unit, as well as looking into a potential barrier to the treatment (comfort, as it is offered under local anaesthetic in an outpatient setting); the study demonstrates that it compares very favourably.
1. Introduction

Miscarriage is known to be the most common complication of early pregnancy (Jurkovic, Overton, & Bender-Atik, 2013), one which can have serious medical consequences should it not be managed appropriately. In situations where medical intervention is indicated, a number of methods have been offered traditionally; these are surgical management of miscarriage (suction curettage under general anaesthesia) and medical management, using misoprostol.

Manual vacuum aspiration (MVA) was described first in the 1970s as a possible method for managing incomplete miscarriage (Milingos, Mathur, Smith, & Ashok, 2009). Since this time, it has been adopted for other uses, including but not exclusively, termination of pregnancy and missed miscarriage (Milingos et al., 2009). Although a popular method of management throughout much of the rest of the world, it has only recently begun to be offered routinely in early pregnancy assessment units (EPAU's) throughout the UK.

MVA is carried out in an out-patient setting and thus does not require hospital admission or a theatre team for management. The procedure is straightforward and can be carried out by doctors and appropriately trained EPAU advanced nurse practitioners. The procedure is performed under local anaesthesia using a self-locking syringe that creates a defined amount of vacuum in order to evacuate the products of conception (Goldberg, Dean, Kang, Youssof, & Darney, 2004; Milingos et al., 2009). Some studies have assessed the outcomes of MVA vs surgical management of miscarriage (SMM) but none have assessed these outcomes alongside patient comfort. The objective of this study was therefore to determine how manual vacuum aspiration compares to surgical and medical management in terms of outcomes and patient comfort within our EPAU.

2. Methods

On diagnosis of early pregnancy miscarriage on ultrasound scan, women were given the treatment options including expectant management (await natural spontaneous miscarriage), surgical management under general anaesthetic (SMM), surgical management under local anaesthetic (MVA) and medical management. This study has evaluated the success and comfort levels of interventional treatments for managing miscarriage including MMM, SMM and MVA. The patients were not randomised and the unit offers each of these management options routinely to patients with confirmed miscarriage/retained products. Risks and benefits of each procedure were offered to each patient and they were given the option to choose one and to change their mind at any point, as per routine consent procedures.

This is a prospective study of 125 patients undergoing either MVA (40 patients), MMM (25 patients) or SMM (60 patients) was carried out over a 6-month period between April and September 2015.

2.1. Patient satisfaction questionnaire

Each of these patients was given a feedback questionnaire at the point of discharge following their procedure (in the case of MVA the questionnaire was completed immediately before leaving the EPAU) that assessed the patient's level of comfort during MVA and MMM and after the procedure for MVA, SMM and MMM. This comfort assessment was a simple scoring system between 1 and 5, where 1 is “very uncomfortable,” 2 is “moderately uncomfortable,” 3 is “some discomfort,” 4 is “little discomfort” and 5 is “no discomfort.” Comfort scores between procedures were then analysed for significance using a simple t-test calculation.

2.2. Success of treatment

A negative urine pregnancy test or a normal ultrasound scan (USS) confirming regular endometrium 2 weeks following the procedure was used as a primary outcome measure of success of the treatment. The secondary outcome measures that were used for analysis included hospital admission when assessing MVA or the length of stay greater than a day when assessing MMM and SMM.
2.3. MMM procedure
On confirmation of a miscarriage on ultrasound scan following a written valid consenting process, women were planned to have MMM in hospital led by an experienced gynaecology nurse. 800 µg of misoprostol was given vaginally and inpatient monitoring with regards to passage of products of conception (POC), vaginal bleeding and analgesic requirement was carried out 6 hours post-administration; this is routine practice in our unit. If there was evidence of POC, women were discharged and advised urinary pregnancy test in 2 weeks’ time. However, in the absence of obvious POC, a USS was arranged in 1 week to confirm completion of miscarriage.

2.4. MVA procedure
On confirmation of a miscarriage on ultrasound scan and following a written valid consenting process, women were planned to have MVA in the procedure room based in the outpatients’ department of the Emergency Gynaecology Unit. They were advised to take oral analgesic including 1 g of paracetamol and/or 400 mg of ibuprofen and self-administer vaginal misoprostol (400 µg) 2 hours prior to the procedure. MVA was undertaken at the allocated time by a consultant. It involved administering 2 ampoules (4 ml) of 1% lidocaine for cervical analgesia and cervix dilated to the desired size of gestational age. A disposable self-locking syringe of 50cc capacity with appropriate sized disposable curette was then used to evacuate the products of conception.

Women were discharged home within 30 min of the procedure. Any hospital admissions or delayed discharges were recorded. Women were then advised to perform a urinary pregnancy test 2 weeks following the procedure. An ultrasound scan was undertaken on those with positive urine pregnancy tests to establish whether there were any retained products.

2.5. SMM procedure
On confirmation of a miscarriage on ultrasound scan and following a written valid consenting process, women were planned to have SMM on the emergency theatre list. They were advised to self-administer 400 µg of misoprostol vaginally at least 1 hour prior to the procedure. SMM involved performing dilatation and suction of products of conception under general anaesthetic in a theatre setting. Following a period of stay in theatre recovery, women were transferred back to the emergency ward and were discharged home on the same day. Any overnight stay in hospital was recorded.

2.6. Statistical analysis
Unpaired t-tests were used to identify statistically significant differences between comfort levels experienced by patients during and after the 3 different procedures. Comfort levels experienced by patients during MMM were compared to those undergoing MVA. Comfort levels after the procedures were compared in all 3 groups (MVA to MMM, MVA to SMM and MMM to SMM).

From the raw data, the mean, standard deviation and range were calculated for each group. Using t-tests to compare each pair of data identified above, a p-value and confidence interval were calculated. Significantly significant differences were identified if p > 0.005 and if the confidence interval did not span zero.

2.7. Ethical approval
All procedures performed in Studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

3. Results
The mean number of gestational age of the 125 patients studied was 8 weeks, the mean age being 33 years old.
Mean intra-procedural comfort scores (Table 1 and Figure 1) were 2.6 for MVA (SD 0.122) and 3.9 for MMM (SD 0.74). There was demonstrable significance difference between these two scores ($p = 0.0025$). Mean comfort scores post-procedure (Figure 1) were 3.95 for MVA (SD 1.09), 3.81 for SMM (SD 1.16) and 4.0 for MMM (SD 0.82). Here we see no significant statistical difference between these scores (MVA vs MMM $p = 0.90$, MVA vs SMM $p = 0.62$).

Percentage delayed discharge rate for MVA was 0%, SMM 13.95% and MMM 57.9%; percentage of failed procedures for MVA was 2.5%, SMM 10% and MMM 68% (Table 1 and Figure 2 Percentage failure and delayed discharge of MMM, MVA and SMM).

### Table 1. Table demonstrating mean comfort scores and % failed procedures/delayed discharges for MVA, MMM and SMM

| Procedure | Nº of Patients | Mean Comfort (during) | Mean Comfort (post) | Failed Procedures (%) | Delayed Discharges (%) |
|-----------|----------------|-----------------------|---------------------|-----------------------|------------------------|
| MVA       | 40             | 2.6                   | 3.95                | 2.5                   | 0                      |
| MMM       | 25             | 3.9                   | 4.0                 | 57.9                  | 68                     |
| SMM       | 60             | N/A                   | 3.81                | 10                    | 13.95                  |

**Figure 1.** Mean comfort scores recorded for MMM, MVA and SMM with standard deviations.

4. Discussion

Currently, MVA is not widely used throughout England and Wales, although it is beginning to be offered more routinely at hospitals throughout these regions of the UK now, with support from the Royal College of Obstetricians and Gynaecologists. This study further supports the existing literature that well establishes the safety and efficacy of MVA as a management option for first trimester miscarriage (Blumenthal & Remsburg, 1994; Goldberg et al., 2004; Greenslade, Leonard, Benson, Winkler, & Henderson, 1993; Milingos et al., 2009), as well as demonstrating that it compares favourably with medical and surgical management of miscarriage in terms of patient comfort and outcomes (efficacy of between 95 and 99% in the literature; this study...
finds 97.5% efficacy) (Association of Reproductive Health Professionals, 2008; Dalton et al., 2006). We are confident that any further presentations necessary would have resulted in the patient re-presenting to our unit as is the case for our SMM and MMM patients; indeed even in the cases where the procedure carried out was unsuccessful, patients reported satisfaction with their management and thus we feel we can be confident that our outcome information is accurate.

Reasons established for “delayed discharge” in the cases of our SMM and MMM patients were all related to pain, PONV and/or bleeding that required (usually) an overnight stay for these symptoms to settle. All delayed discharges in the case of SMM were due to bleeding that subsequent USS demonstrated RPOC post procedure and thus the patients required a second procedure (surgical electric curettage again all cases).

As well as the previously discussed efficacy in terms of outcomes, the literature also suggests a significant benefit in terms of cost and the subsequently “free” space in theatres not taken up by SMM’s, due to the ability of this procedure to be carried out in the outpatient setting (Association of Reproductive Health Professionals, 2008; Blumenthal & Remsburg, 1994; Dalton et al., 2006; Milingos et al., 2009). One study has demonstrated that patient satisfaction, particularly in terms of comfort, compares favourably between MVA and SMM; a result that is also replicated in this study (Dalton et al., 2006).

Given the increasing amount of data in the literature demonstrating the benefits of MVA to patients and healthcare organisations, the uptake of this procedure by patients is still fairly low. It has been suggested that patient anxiety over local anaesthesia and staff competencies may contribute to this perceived aversion (Milingos et al., 2009) or possibly due to poor accessibility until recently. We believe that this study will help alleviate some of these perceived anxieties and add to the substantial evidence base supporting this procedure.

5. Conclusion
MVA has once again been demonstrated to be a safe and effective method for the management of first trimester miscarriage, compares favourably in terms of patient comfort and we fully support the increase in accessibility to this procedure for the management of first trimester miscarriage.
Abbreviations

MVA  Manual Vacuum Aspiration
SMM  Surgical Management of Miscarriage
MMM  Medical Management of Miscarriage
ERPC  Evacuation of Retained Products of Conception
PONV  Post-operative Nausea and Vomiting
USS  Ultrasound Scan

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Author details

Oscar MacCormac1,2
E-mail: oscar.maccormac@nhs.net
ORCID ID: http://orcid.org/0000-0002-2938-543X

Alexandra Edwards3
E-mail: alexandra.edwards1@nhs.net

Murray Forsyth1
E-mail: murray.forsyth@nuh.nhs.uk

Fanny Ti1
E-mail: fanny.ti@nuh.nhs.uk

Shilpa Deb1
E-mail: shilpa.deb@nuh.nhs.uk

1 Department of Gynaecology, Queen’s Medical Centre, Nottingham, Derby Road, Nottingham NG7 2UH, UK.
2 Department of Neurosurgery, Imperial College Healthcare NHS Trust, St Mary’s Hospital, Praed Street, London W2 1NY, UK.
3 Department of General Surgery, Torbay Hospital, Lowes Bridge, Torquay, Torbay TQ2 7AA, UK.

Consent
Informed consent was obtained from all individual participants included in this study; each patient was offered each procedure as detailed in “methods” and consent was documented for participation in the study—the option to withdraw was given to each patient and this could be actioned at any point prior to publication.

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