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ORIGINAL ARTICLE

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First trimester MTP using MVA: Report of a FOGSI multicentric Study across 27 clinics

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OBJECTIVE(S) : To study the experience of Indian doctors in the use of manual vacuum aspiration (MVA) for voluntary termination of pregnancy (MTP) during the 1st trimester and in particular after 8 weeks of pregnancy.

METHOD(S) : Twenty seven purposively selected centers in nine cities and towns across the country reported on 1686 MVA procedures done over a 4-6 month period during 2004. Of the 1686 MVA procedures reported 1203 (71.3%) were for MTP and 36% of the MTPs were for pregnancies of over 8 weeks.

RESULTS : Incomplete abortions and other complications were reported in 2.9% of cases (2.1% of cases below 8 weeks and 4.5% above 8 weeks). Most procedures irrespective of gestation period were completed in less than 15 minutes. Over half of all the cases were successfully managed under local anesthesia and/or sedation. Use of check curettage did not decrease the rate of incomplete abortion.

CONCLUSION(S) : Even in diverse service delivery settings, MVA is a safe and effective procedure that can be used throughout the first trimester of pregnancy.

Key words : manual vacuum aspiration, (MVA), voluntary termination of pregnancy (MTP), safety of induced abortion, provider experience

Introduction

Vacuum aspiration (electric and manual) is a recognized method recommended for pregnancy termination throughout the first trimester and WHO recommends that it replace sharp curettage (D and C) wherever possible [1]. The safety and efficacy of vacuum aspiration is already well proven. Manual vacuum aspiration (MVA) is as effective as electric one and has the additional advantages of portability, ease of use as an outpatient procedure with minimal anesthesia, and nondependence on electricity enabling its application in areas where power outages and erractic supply are commonplace [2-5].

MVA use is widespread the world over and has been gaining ground in India in recent years. The federation of Obstetric and Gynecological Societies of India (FOGSI) is collaborating with WHO and the Government of India to pilot the integration of MVA into the Primary Health Center level in a project that spans two districts each in eight states across the country. Unfortunately, many doctors in the country remain hesitant to use MVA, especially in gestations of over 8 weeks. Some providers view the aspirator as cumbersome or clumsy in large part because of the experiences with the single valve menstrual regulation (MR) aspirators available in India in the early 1970s and the fact that documentation on more recent Indian experience with MVA has been sparse.

The present study was undertaken to fill this information gap by documenting the experience of Indian doctors with the use of MVA for MTP in the 1st trimester especially after 8 weeks of pregnancy.

Methods

The study was designed to be an observational descriptive case series. Participating centers were purposively selected

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from among those clinics/hospitals that were using the MVA procedure either predominantly or partially to manage first trimester elective abortion, were legally certified MTP centers, had significant case loads, and were willing to participate and maintain records of all cases as per the study protocol. Since a complete listing of all providers in the country using MVA was not possible the selection of sample was necessarily one of convenience as opposed to a true random sample. Care was however taken to ensure that the 27 selected centers were spread across geographic regions and included both private sector and public sector facilities (Table 1).

The study was conducted from January to December 2004. Participating centers maintained case records of all women who underwent an MVA procedure for terminating a 1st trimester pregnancy at their center during the study. Obstetric history, information related to the actual procedure, observed complications, and a report of follow up visits were recorded for each woman. The service providers filled an additional questionnaire at the end of the study to record their overall experiences with MVA.

The study underwent an ethical review at Ipas as well as by local Ethics Committees if they existed at individual centers. Even though no individual identity information was collected nor were women actually interviewed, all women were informed of the study and purpose of data collection, and that the case information was included only if they consented to it.

Since this was an observational study, there were no preset inclusion or exclusion criteria for case selection; each center was allowed to follow its own criteria regarding when to perform an MVA. No standardization was insisted on with relation to use of pain control medication, cervical priming, administration of prophylactic antibiotics etc. At private clinics the MVA procedures were done by a single senior obstetrician and gynecologist. More than one operator was involved in service provision at public facilities and teaching hospitals, usually the head of the department or unit as well as another professor of Obstetrics and Gynecology and sometimes a resident doctor experienced in MVA use. Although all centers were already using MVA, for the purposes of the study, each center was given one or more new double valve manual vacuum aspirators to minimize variations due to instrument maintenance or wear and tear and to allow some judgments to be made on instrument reusability.

The principal investigators of all study centers attended prestudy meetings to discuss study protocols and questionnaires and to agree on standardized reporting formats. A part time study coordinator coordinated collection, collation, and periodic reviews of data from the sites. SPSS 13.0 was used for data entry, cleaning and analysis.

Results

A total of 1686 MVA procedures were reported. The distribution of cases reported across regions and across types of hospitals is shown in Table 1. Of the total reported cases 1203 (71.3%) were for MTP, the remaining 483 (28.7%) being for other indications like incomplete abortion, missed pregnancy, and molar pregnancy. In this paper only MTP cases are analyzed.

Table 1. Participating centers and number of reported cases.

	Participating centers (n=27)	MVA procedures (all indications) (n=1686)
Type of Hospital		
Private + NGO	16	962 (57.1)
Public (State/Central Govt/ Municipal Corporation)	11	724 (42.9)
Geographic Distribution		
Western region	11	709 (42.1)
Southern region	4	261 (15.5)
Eastern region	7	(381 (22.6)
Northern region	5	(335 (19.8)

Figures in brackets represent percentages
NGO - Nongovernment organization.

The induced abortion was the first pregnancy for 6.7% of women (Table 2). One hundred and five women (8.9%) had at least one previous MTP and 74 (6.3%) a previous spontaneous abortion. Just over a third of the reported cases were over 8 weeks duration of pregnancy (Table 2). The proportions of higher gestation cases were significantly higher in public hospitals (44.1%) as compared to other centers (28.3%).

Table 2. Gravidity and duration of pregnancy.

	Number of Cases (%)	Percent
Gravidity	(n=1174) [a]	
1		6.7
2		83.6
≥ 5		9.7
Duration of pregnancy (weeks)	(n=1201) [b]	
≤ 8		64.0
8 - 12		35.1
≥ 12		0.9

[a] Information missing for 29 cases [b] Information missing for 2 cases

Specifics of how the MTP procedure was carried out varied across sites and by case. Cervical priming was used in 61.3% of cases under 8 weeks of gestation and in 83% of cases over 8 weeks (P<0.0001). Fifteen methyl PGF_2 alpha was the commonest priming agent reported across gestations and was used in 56.7% of all cases where priming was done. Misoprostol was used in 40.3% of cases. Laminaria tents were used for a small fraction of cases (1.33%) and only at one center. Cervical dilation was required in 94.7% of all cases. Dilation was done by plastic cannulas in 80.5% of cases and by metal dilators in the remaining. Both had to be used in 3.3% of cases. Irrespective of whether metal dilators or plastic cannulas were used 8 mm was the most commonly mentioned largest size dilator used for pregnancies of less than 8 weeks duration. Among higher gestation age cases, 10 mm was the largest size of dilator most commonly used. MVA was accompanied by tubal ligation (TL) in 327 cases (27.2%) and by insertion of an intrauterine contraceptive device (IUCD) in 295 (24.5%). 69.7% of MVA abortions in the public sector were accompanied by an IUCD insertion or TL. In the private clinics only 27% were accompanised by an IUCD insertion or TL.

Over half the cases (55.9%) were managed using intramuscular or intravenous sedation and/or local anesthesia and seven centres relied exclusively on these measures for all reported procedures. There was no significant difference in the use of these types of pain control measures based on pregnancy duration (Table 3). Spinal anesthesia was used at five centers only and 89.6% of women in whom spinal anesthesia was used underwent a concurrent TL. Use of general anesthesia (GA) was more widespread with six centers using it as a routine for all the reported procedures and a further 14 centers using it for at least some of the cases. A concurrent TL was done in only 22.2% of cases where GA was used. Use of GA was significantly higher among private / nongovernment organization (NGO) clinics (58% of all MVA procedures) than at public hospitals (16.8% of all procedures).

Table 3. Anesthesia / sedation used.

	Duration of pregnancy	
	< 8 weeks (n=763) [a] Percent	> 8 weeks (n=432) [b] Percent
General anesthesia	43.5 [c]	29.4 [c]
Spinal anesthesia	2.8	10.9
Local anesthesia	29.2	26.6
Intravenous sedation	18.5	24.3
Intramuscular sedation	6.0	8.8

[a] Information missing for 5 cases [b] Information missing for 1 case
[c] P<0.0001

Time taken to complete the procedure was defined as the time from insertion of the speculum to the completion of evacuation. As Table 4 indicates, length of procedure depended on pregnancy duration. However nearly all procedures (96.6%) were completed in less than 15 minutes. Reestablishing the vacuum or recharging the aspirator was needed significantly more often in cases with higher gestation, usually because the aspirator became full before the products were completely evacuated. Service providers varied in how they judged completeness of the procedure (Table 4). All but four centers used check curettage at least some of the times. Ten of the 27 centers used check curettage in over half the procedures done, five of these using it in over 80% of cases.

Table 4. Procedure related variables.

	Duration of pregnancy		
	8 weeks Percent	> 8 weeks Percent	P-value [a]
Time required (minutes)			
< 5	50.3	26.1	<0.0001
5-15	48.6	66.3	<0.0001
> 15	1.0	7.6	0.05
Need for recharging the aspirator	39.6	72.4	<0.0001
Completeness of procedure by			
Visual inspection of products of conception	66	65.4	
Check curettage	45.4	57.9	
Ultrasound	6.8	5.8	

[a] Chi square test or t test

Centers reported on incomplete abortions (measure of effectiveness) and on any other complications observed during the procedure or noticed at the follow up visit 3-15 days post procedure as per WHO guidelines [1]. Complete evacuation with MVA was possible in 99.5% of cases of $\leq$ 8 weeks gestation and in 98.2% with higher duration of gestation. Including incomplete abortion, complications were reported in 35 (2.9%) cases. Table 5 shows the types of complications reported and their distribution across pregnancy duration. Reported complications did not vary by the number of past pregnancies but were marginally higher in women with a previous MTP (5%) compared to those in women without a previous MTP (2.8%). Complication rates were similar in private and public hospitals and across geographic regions. Complications were lower when cervical priming was used (2.3% vs 4.3%) but the difference was not statistically significant. Use of check curettage did not decrease the rates of reported incomplete abortion. Significantly higher complication rates were seen in cases where general anesthesia was used. Concurrent TL or IUCD insertion did not increase the complication rates.

Table 5 Complications.

Complication	Duration of pregnancy		P value [a]
	≤ 8 weeks (n=754) percent	> 8 weeks (n=426) percent	
Incomplete abortion	0.5	1.8	0.035
Uterine perforation	0.3	0.2	
Cervical tear	0.7	0.9	
Excessive bleeding	0.8	2.3	0.028
Other	0.001	0.002	
All	2.1	4.5	0.023

[a] Chi square test or t test

More than one complication reported in some cases.

In order to adjust for confounding effect and see the independent effect of all of the above variables, a logistic regression analysis with reported complications being the dependent variable was performed. The significant variables that were retained in the logistic regression as influencing complication rates were, pregnancy duration of over 8 weeks (OR 1.4; 95% CI 1.1-1.7) and the use of general anesthesia as compared to local anesthesia (OR 1.8; 95% CI 1.3-2.1).

Difficulties with instrument use were reported in 1.8% of all procedures done at ≤ 8 weeks gestation and in 4.9% done at > 8 weeks gestation. Most commonly mentioned difficulties were with dilation using the plastic cannulas, the tip of the cannula bending or the cannula getting detached from the syringe. Information on overall experience with the use of equipment was available from 14 centers. Three of these mentioned that the aspirator given to them at the start of the study had to be refurbished (after 52, 60 and 70 procedures respectively), in two centers because of O ring malfunction and in one because the collar stop needed to be replaced. Six centers said that one or more cannulas had to be replaced during the study. Most common reason for this was that the cannulas got worn out. Other reasons for replacements were cannulas became too rigid or cracked, the aperture became too narrow, and that the adapter would not fit into the cannula. Most providers found the instrument easy and comfortable to use, though service providers at three centers felt that the recharging of the syringe required at gestations of more than 8 weeks was a problem and one provider said that he had many incomplete abortions at higher gestatons.

Discussion

The selected centers were not a true random sample of all MVA users in India and hence the findings cannot be generalized beyond the study sample.

The distribution of cases across gestation does not represent the distribution of cases coming to the hospital as service providers were free to use other methods of termination as well. The proportion of cases beyond 8 weeks may be disproportionately higher as in some centers medical abortion for only lower gestations was in common use. The later gestations at which women come to government hospitals is known and may account for the higher proportions of later first trimester cases seen at such hospitals in this study as well.

Even at pregnancy durations of higher than 8 weeks, the majority of procedures were completed within 15 minutes and while the rates of incomplete abortion and excessive bleeding were higher effectiveness was high and complication rates were well within the range of those reported in other international studies. Check curettage did not offer any advantage and this argues for the reduction in its routine use after MVA procedure [1].

While small numbers may have prevented statistical significance, cervical priming does seem to decrease complication rates. It is important to note that a concurrent tubal ligation or IUCD insertion did not have any effect on the proportion of reported complications. Local anesthesia and/or sedation was successfully used in over half of all the cases even at higher gestations and is consistent with similar successful use elsewhere [5].

Conclusion

Despite some limitations, the study has demonstrated that even in real life service delivery settings with their inherent variations in clinical practice, instrument handling, case selection criteria, and comfort levels of service providers using the equipment, MVA is an effective procedure with few complications and can and is being used safely throughout the first trimester of pregnancy. This evidence is even more significant in the light of the amendments in the MTP rules in 2003 rationalizing requirements for first trimester MTP service provision thus providing an excellent opportunity to expand access to safe abortion through the use of this technology.

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Declaration of Vested Interests

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