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Gestational dating using last menstrual period and bimanual exam for medication abortion in pharmacies and health centers in Nepal

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Abstract

Objective: To evaluate whether conducting a bimanual examination prior to medication abortion (MAB) provision results in meaningful changes in gestational age (GA) assessment after patient-reported last menstrual period (LMP) in Nepal.

Study Design: Women ages 16–45 (n=660) seeking MAB at twelve participating pharmacies and government health facilities, between October 2014 and September 2015, self-reported LMP. Trained auxiliary nurse midwives assessed GA using a bimanual exam after recording LMP. We compared GA assessments as measured via patient-reported LMP alone versus via LMP plus bimanual exam.

Results: Overall, 660 women (326 at pharmacies, 334 at health facilities) presented for MAB, and 95% were able to provide an LMP. Overall agreement between LMP alone and LMP with bimanual exam was 99.3%. If LMP alone had been used without bimanual exam, fewer than one in 200 women would have been given MAB beyond the legal gestational limit. Among the three women who were ≤ 63 days by LMP but >63 days by bimanual exam, only one would have

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received MAB beyond 70 days gestation. Fewer than one in 600 women would not have received MAB care when eligible by adding a bimanual exam.

Conclusion: There was high agreement between LMP alone and LMP plus bimanual exam. Routine bimanual exam may not be essential for safe and effective MAB care for women who are able to report an LMP. Removing the bimanual exam requirement could decrease barriers to provision outside of currently approved clinical settings and allow for expanded abortion access through provision by providers without bimanual exam training or facilities.

Implications: Routine bimanual exams may not be essential for safe medication abortion provision by trained clinicians in pharmacies and health facilities in low resource settings like Nepal.

Keywords

bimanual exam; gestational age; last menstrual period; medication abortion; mifepristone; Nepal

1. Introduction

Efforts to increase access to safe mifepristone-misoprostol medication abortion (MAB) worldwide have included broadening the provider base, expanding the types of facilities where abortion can be provided, and simplifying the regimens and requirements for provision [1–3]. In Nepal, where abortion was decriminalized in 2002, access to care has improved significantly, in part through implementation of these mechanisms [4]. Nevertheless, many women continue to obtain clandestine and unsafe abortion care [5]. Physicians, as well as nurses and auxiliary nurse midwives with training as a skilled birthing attendant, are authorized to provide MAB services through 63 days gestation in Nepal [2, 6]. Currently, MAB can only be provided legally in government-certified health facilities. Expanding the types of facilities at which services are provided, such as pharmacies, has the potential to further improve access to MAB [7]. Mifepristone and misoprostol are widely available at many pharmacies [8], and pharmacies are more accessible than health facilities in many communities worldwide, particularly in rural areas. Whether a bimanual exam adds clinically useful information for a patient seeking MAB outside of a health facility, who has already reported her last menstrual period (LMP), is unknown.

Routine use of ultrasound prior to MAB is not recommended by the World Health Organization (WHO) safe abortion guidelines [9]. Accordingly, the Nepali protocol for provision of MAB relies on last menstrual period (LMP) with confirmation by bimanual exam for dating assessment [6]. Ultrasound is also not routinely recommended for dating assessment in many other low resource settings where guidelines for abortion care are publically available, including Ethiopia [10], South Africa [11], India [12], Mexico City [13] and Cambodia [14]. LMP has been shown to correlate with bimanual exam assessment. Among women in India, self-reported LMP was within 2 weeks of estimates by clinicians' bimanual exam 94% of the time [15].

If provision of MAB were expanded outside of health facility settings, it would be important to first establish that GA could be determined by LMP alone without a bimanual exam.

Many pharmacies in Nepal have a private room for patient consultation where bimanual exams can be conducted, but many pharmacies in Nepal and worldwide do not. Removing the bimanual exam requirement could decrease barriers to provision outside of currently approved clinical settings and potentially allow for provision by providers without bimanual exam training or facilities.

We conducted a non-inferiority study to investigate the safety and effectiveness of MAB provided by trained auxiliary nurse midwives from pharmacies compared to public health facilities in Nepal [16]. The study found that MAB was no less safe or effective when provided from pharmacies compared to public health facilities when bimanual exams were conducted in both settings. In this pre-specified secondary analysis, we evaluated whether conducting a bimanual examination changed the GA assessment after a patient reported an LMP. We also assessed whether ability to estimate GA without bimanual exam differed by provision setting. We hypothesized that adding a bimanual exam would not have a clinically meaningful effect on estimation of GA, supporting efforts to simplify provision and remove the bimanual exam requirement, and would not be affected by practice setting, supporting efforts to decentralize provision.

2. Materials and Methods

This study was conducted between October 2014 and September 2015 in the Chitwan and Jhapa districts of Nepal. All women seeking a MAB at one of six participating pharmacies or six government-certified public health facilities were screened for MAB eligibility, per standard government protocol. Clinicians involved in the study were all auxiliary nurse midwives who provided care at both pharmacies and public health facilities prior to the study and were trained on the study protocol. The auxiliary nurse midwives used a standardized form to record patient demographics, reproductive history, MAB contraindications, and estimation of GA based on patient-reported LMP. Auxiliary nurse midwives used menstrual wheels as needed to estimate GA based on LMP (if reported) and recorded it prior to conducting the bimanual exam to avoid contamination of the LMP alone-based data. The auxiliary nurse midwife then performed a physical exam including a bimanual exam; an estimated GA based on uterine size was recorded. Auxiliary nurse midwives were aware of patient-reported LMP when completing the bimanual exam. All participating pharmacies had a private exam room adjacent to the pharmacy where the exam took place.

Women who were eligible to receive MAB, and for participation in the MAB safety and effectiveness study [16], provided informed consent (n=605); we also received approval to collect de-identified clinical data on patients presenting to these sites for MAB care who did not receive a MAB (n=55). The study sample size was based on assessing non-inferiority of the effectiveness of MAB in pharmacies vs. public facilities, accounting for clustering [16]. The University of California, San Francisco, Committee on Human Research and the Nepal Health Research Council approved the protocol.

2.1 Measures.

The primary outcome of our study was GA of pregnancy assessed by study clinicians in two ways: via patient-reported LMP alone and via LMP plus clinician bimanual exam (or bimanual exam alone if the patient could not report an LMP). Because the GA limit for MAB in Nepal is 63 days, we created dichotomous versions of each GA variable (<63 days, >63 days).

2.2 Analyses.

We described patient characteristics and, to assess differences by facility type, used a series of mixed-effects linear and logistic regression models, accounting for clustering by facility and auxiliary nurse midwife. We described assessments of GA based on LMP and LMP with bimanual exam, and examined facility type differences using mixed-effects regression. We calculated κ statistics as a measure of concordance between dating by LMP <63 days and LMP with bimanual exam <63 days, using bootstrapping to calculate confidence intervals that accounted for the clustered data structure. (We did not calculate predictive values because bimanual exam may not be considered a “gold standard” measure.) Analyses were completed using STATA version 14.2 (STATA Corp LP, College Station, TX).

3. Results

Overall, 660 women presented at participating facilities for MAB during the one-year study: 326 women at pharmacies, 334 women at public health facilities. Women were on average 28 years old and had had an average of two live births (Table 1). Over 99% were married. There were no statistically significant baseline differences between the women who presented at pharmacies compared to public health facilities.

Of the 660 patients, 627 (95%) were able to report the first day of LMP [308 (95%) women at pharmacies and 319 (96%) women at public health facilities, $p=0.76$] (Table 2). Among women who reported an LMP, mean GA by LMP was 47.7 days (range: 30–100 days). There was no significant difference by facility type ($p=0.99$). Thirty-seven women (5.9%) estimated their GA to be greater than 63 days by LMP (15 at pharmacies and 22 at public health facilities, $p=0.49$).

Mean GA by bimanual exam was 47.0 days (range: 34–112 days). There was no significant difference by facility type ($p=0.42$). Forty-seven women (7.1%) had a bimanual exam that estimated the pregnancy to be >63 days, making them ineligible for MAB by Nepal’s guidelines (20 women at the pharmacies and 27 women at the health facilities, $p=0.38$).

Among the 33 women who reported “not sure” to LMP, the mean GA by bimanual exam was 52.5 days (range: 35–98 days). Eight (24%) of them had a GA estimated by bimanual exam to be >63 days.

Three women (0.5% overall) were <63 days based on LMP but >63 days by bimanual exam (two at the pharmacies and one at the public health facilities) (Table 3; Figure 1). All three women were between 69 and 72 days GA by bimanual exam. These three women were ages 20–35, reported their GA by LMP to be between 38 and 63 days, had 1–3 living children,

and had a BMI of 18–26. One woman overall (<0.2%) estimated her GA to be greater than 63 days but was found to be 63 days by bimanual exam. The overall percent agreement between LMP alone and LMP with bimanual exam was 99.3%. There was concordance of estimated GA by LMP 63 days and estimated GA by LMP with bimanual exam 63 days for 587 women (93.6%), and estimated GA by LMP greater than 63 days and estimated GA by LMP with bimanual exam greater than 63 days for 36 women (5.7%) with a kappa coefficient of 0.93 [95% CI: 0.92–0.95], $p < 0.001$.

All participating auxiliary nurse midwives were female and reported a median of 16 years (range 6–34) practicing. Auxiliary nurse midwives had a median of five years' experience (range 3–5) providing MAB [16].

4. Discussion

We compared an assessment of GA using LMP alone to the current standard of bimanual exam, plus LMP if reported, among women seeking MAB from trained clinicians at twelve facilities in Nepal. There was concordance of estimated GA by LMP 63 days and estimated GA by LMP with bimanual exam 63 days, and the overall percent agreement was 99.3%. We found that if no bimanual exam had been completed, and LMP alone had been used to estimate GA, among the 95% of women able to report LMP, fewer than one in 200 women would have been given MAB when she was actually beyond the GA limit and fewer than one in 600 women would not have received MAB care when she could have received it. Among the women unable to report an LMP, 25 would have been referred to a health facility for care if a bimanual exam were not available when they could otherwise have received MAB. Assessment of GA was no less accurate when conducted by trained clinicians in pharmacy settings as in public health facilities.

Under the model of MAB care implemented in this study, the additional risk of incomplete abortion for women would likely have been relatively minor had no bimanual exam been performed. Auxiliary nurse midwives at pharmacy sites had a health facility available for referrals. If bimanual exam had not been available at the pharmacy, women who were unable to report an LMP or whose LMP was beyond 63 days could be referred to a health facility for a bimanual exam. Among the three women who were 63 days by LMP but >63 days by bimanual exam, only one would have received a medication abortion beyond 70 days gestation based on bimanual exam, and her pregnancy was estimated to be 72 days gestation. Mifepristone-misoprostol MAB has been shown to be safe and effective (with efficacy up to $\geq 93\%$) through 70 days; it is thus unlikely that any woman would have been provided a MAB outside of a reasonable evidence-based standard of care [17]. This one woman may have been at a small increased risk of requiring referral to the health center for an incomplete abortion requiring uterine evacuation.

Our finding that GA can be estimated accurately by nurses using LMP alone is consistent with research from other settings [18, 19], and extends the finding to the pharmacy setting. For example, among women seeking abortion in India, only four of 173 women who estimated their GA to be 10 weeks based on LMP were actually >10 weeks based on provider estimates using bimanual exam (2.3%) [15]. Among 365 women in Maldives,

Mexico and the US who underwent MAB without a bimanual exam or ultrasound, only 1% required an aspiration and only 1% had a serious adverse event [20].

Our study has several limitations. We did not verify bimanual exam assessments using ultrasound. Ultrasound, however, is not currently recommended prior to MAB either by WHO or Nepali abortion guidelines [6, 9], and bimanual exam has been shown to be accurate at predicting ultrasound-based GA [21, 22]. In addition, using bimanual exam to estimate GA, the WHO-recommended standard of care, is more clinically relevant than ultrasound in settings like Nepal where ultrasound is rarely used. Routine use of ultrasound has been shown to increase the number of women who would be eligible for MAB [23] so our findings that GA calculated by LMP alone did not limit access is likely conservative. Because bimanual exam was used without ultrasound, we are unable to assess the validity of our bimanual exam estimates. Auxiliary nurse midwives in our study were highly experienced, however, reporting a median of 16 years practicing, a practice which requires frequent use of bimanual exam for pregnancy dating. Because providers in this study were trained auxiliary nurse midwives with substantial prior experience providing MAB and assessing gestation, results may not be generalizable beyond experienced, well-trained auxiliary nurse midwives.

We recorded GA by bimanual exam in days for comparability to LMP-based reporting, though we acknowledge that use of days implies a level of specificity unrealistic for a bimanual exam [24]. In addition, Nepali women may be particularly aware of their exact LMP given socio-cultural practices which restrict women's activities during menstruation. It is unknown whether these findings are generalizable to other settings without similar customs around menstruation. Auxiliary nurse midwives may have asked women about menstrual regularity but it was not documented in our data collection. It would be important to confirm that women have regular periods before forgoing a bimanual exam prior to medication abortion in practice.

Notably, women in the study may have known they would undergo an exam to confirm their reported LMP date and thus reported more accurately than they otherwise would have. Women who are aware that their reports will not be confirmed via exam may under-report GA in order to receive desired medication abortion care. We found that bimanual exam assessment disagreed with LMP alone in only a few cases, but these findings may not be generalizable to clinicians with more or less experience estimating GA.

The strengths of this study are that it is the first that we are aware of to assess whether auxiliary nurse midwives can accurately estimate GA among women presenting to pharmacies for MAB based on LMP alone. The study was set in twelve pharmacies and health facilities across two districts in Nepal, so includes a diverse population from within Nepal. Data were collected prospectively and within the context of a clinical study, avoiding problems with inaccuracy and variation in clinical record-keeping.

WHO recommendations on health worker roles in expanding access to safe abortion conclude that abortion care can be safely provided by properly trained clinicians, including nurses [25]. This study supports the ability of trained auxiliary nurse midwives to assess GA

at pharmacy locations without using bimanual exam. Expanding MAB services to pharmacies could leverage a trained and approved workforce to provide care in a setting that is easily accessible to women within their communities. Formal evaluations of whether auxiliary nurse midwives could provide medication abortion effectively and safely without a bimanual exam in pharmacies are needed. Such efforts should be accompanied by an evaluation of patient and provider acceptability of providing MAB without a bimanual exam.

Our findings are not generalizable to provision of MAB by other health care providers such as pharmacists or community health workers (CHWs). In a study that provided training to dispense MAB to pharmacy workers in Nepal, the risk of incomplete abortion was low (<5%) and there were no serious complications among the 992 abortion clients [3]. In a study assessing the ability of CHWs in Nepal to screen women for abortion eligibility, CHWs were able to use a dating wheel and eligibility checklist well compared to trained abortion providers [26]. CHWs in South Africa were able to assess whether women were eligible for medication abortion using LMP 88% of the time compared to ultrasound [19]. Trained pharmacists in Nepal were able to dispense medication abortion to 992 women safely and effectively with no serious complications [27].

Expansion of MAB provision by pharmacists and CHWs in low resources settings worldwide warrants further study. The WHO guidelines on task-sharing in abortion care highlight that “well designed and rigorous research” is needed to understand whether these two groups of providers are able to assess eligibility, administer the medications and manage side effects, and assess for abortion completion before recommendations can be made to support provision by these two groups [28].

Routine bimanual exam may not be essential to safe provision of MAB by trained clinicians in pharmacies and public health facilities. Removing the requirement for a bimanual exam, particularly among women who are certain that their LMP is below the eligible threshold, may expand both the number of facilities where MAB could be offered and the type of providers that could offer MAB. Expanding MAB access has the potential to decrease maternal morbidity and mortality, particularly in low resource settings like Nepal.

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Figure 1. Gestational Age estimated by last menstrual exam compared to bimanual exam
Lines indicate 63 days gestation. Circled dots represent women who were 63 days based on LMP but >63 days by bimanual exam and the woman who was greater than 63 days but was found to be 63 days by clinician bimanual exam.

Table 1.

Characteristics of participants seeking medication abortion in pharmacies and public health facilities

	Total (N=660)	Pharmacies (N=326)	Public Health Facilities (N = 334)	P-value*
Age , mean yrs (SD)	27.6 (5.9)	27.3 (5.9)	27.9 (5.9)	0.36
BMI , mean (SD)	22.6 (3.3)	22.7 (3.5)	22.5 (3.1)	0.50
Education , mean yrs (SD)	7.2 (4.1)	7.5 (4.1)	6.8 (4.2)	0.07
Currently married , n (%)	654 (99.1)	321 (98.5)	333 (99.7)	0.14
Live births , mean (SD)	1.9 (1.2)	1.7 (1.2)	2.0 (1.3)	0.08
Prior induced abortions , n (%)				0.92
None	434 (65.8)	212 (65.0)	222 (66.5)	
1	177 (26.8)	89 (27.3)	88 (26.4)	
≥2	49 (7.4)	25 (7.7)	24 (7.2)	
Caste , n (%)				0.36
Brahman/Chettri (high)	297 (44.9)	148 (45.4)	148 (44.3)	
Janajatis (indigenous)	286 (43.3)	148 (45.4)	38 (41.3)	
Dalit (untouchable)	78 (11.8)	30 (9.2)	48 (14.4)	

*Mixed-effects regression was used to account for clustering in the assessment of differences

Table 2.

Estimated gestational age (GA) by reported last menstrual period (LMP) and bimanual exam among women seeking medication abortion in pharmacies and public health facilities

	Total (N=660)	Pharmacies (N=326)	Public Health Facilities (N = 334)	P-value
Last menstrual period (LMP)				
Participant was able to report her LMP, n (%)	627 (95.0)	308 (94.8)	319 (95.5)	0.76
GA by self-reported LMP, mean days (SD) (n=627)	47.7 (10.1)	47.7 (9.8)	47.7 (10.4)	0.99
GA by LMP >63 days, n (%) (n=627)	37 (5.9)	15 (4.8)	22 (6.9)	0.49
Bimanual exam				
GA by clinician bimanual exam, mean days (SD)	47.0 (10.1)	46.6 (9.3)	47.4 (11.0)	0.42
GA by clinician bimanual exam >63 days, n (%)	47 (7.1)	20 (6.1)	27 (8.1)	0.38

Table 3:

Agreement between reported last menstrual period (LMP) and bimanual exam to assess gestational age among women seeking medication abortion in pharmacies and public health facilities who were able to report an LMP (n=627)

		Bimanual exam	
		≤ 63 days	> 63 days
LMP	≤ 63 days	587 (93.6)	3 (<0.5)
	>63 days	1 (<0.2)	36 (5.7)

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