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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 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.

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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].

☆ Conflict of Interest: None.
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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, College Station, TX, USA).

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=.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=.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=.49).

Mean GA by bimanual exam was 47.0 days (range: 34–112 days). There was no significant difference by facility type (p=.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=.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.

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. (S.D.)	27.6 (5.9)	27.3 (5.9)	27.9 (5.9)	.36
BMI, mean (S.D.)	22.6 (3.3)	22.7 (3.5)	22.5 (3.1)	.50
Education, mean y (S.D.)	7.2 (4.1)	7.5 (4.1)	6.8 (4.2)	.07
Currently married, *n* (%)	654 (99.1)	321 (98.5)	333 (99.7)	.14
Live births, mean (S.D.)	1.9 (1.2)	1.7 (1.2)	2.0 (1.3)	.08
Prior induced abortions, *n* (%)				.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 (%)				.36
Brahman/Chettri (high)	297 (44.9)	148 (45.4)	148 (44.3)	
Janajatis (indigenous)	286 (43.3)	148 (45.4)	138 (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.

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