

Original research article

# Medical abortion can be provided safely and effectively by pharmacy workers trained within a harm reduction framework: Nepal ☆,☆☆,★,★★,☆☆☆

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## Abstract

**Objectives:** To examine the treatment efficacy, safety and satisfaction of women using medical abortion (MA) pills provided by pharmacists following an education intervention based on a harm reduction approach.

**Study design:** This was an operations research study over a six-month period in 2015, using a non-inferiority design. We provided training to dispense MA pills, based on a harm reduction approach, to a group of pharmacy workers in Makwanpur district (GROUP 2). We compared selected outcomes with women who bought the pills from pharmacy workers in Chitwan district (GROUP 1), who had received similar training in 2010. The primary endpoint measured in 992 women in both districts was complete abortion within 30 days of using the pills. We assessed the efficacy of MA (self-reported complete abortion) and safety (no reported adverse event). To determine complete abortion, we asked women about passage of the products of conception, cessation of abdominal cramps, vaginal bleeding, need for manual vacuum aspiration or repeated doses of misoprostol. We used a four-point Likert Scale to determine level of satisfaction with MA use. Pearson Chi-Square test was used to examine any differences in proportion of complete abortions between women who were served by the two groups of pharmacy workers.

**Results:** The difference in the rate of complete abortions between the two groups of women, 96.9% and 98.8%, was not statistically significant. The women reported no serious complications, and there was little difference in their satisfaction levels.

**Conclusions:** Trained pharmacy workers dispensed MA safely and effectively to the satisfaction of almost all women clients, and the positive results of training had continued several years later.

**Implications:** The role of pharmacy workers as providers of correct and complete information on safe and effective use of MA needs to be recognized and policies formulated to allow them to provide MA drugs for first trimester use.

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**Keywords:** Medical abortion provision; Pharmacy worker; Training; Safety; Effectiveness; Client satisfaction

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## 1. Introduction

Medical abortion using a combination of mifepristone and misoprostol has been shown to be widely acceptable to women in both developed and developing countries [1–4]. The World Health Organization recommends a regimen for pregnancies up to 9 weeks of 200 mg of mifepristone administered orally, followed 24–48 h later by 800 mcg of misoprostol administered vaginally, buccal or sublingually. For oral administration, the recommended dose of misoprostol is 400 mcg for gestations up to 7 weeks [5]. In recent years, evidence of the safety and effectiveness of medical abortion (MA) has resulted in the simplification of the appropriate standards and health worker skills required for its provision.

The World Health Organization published a guideline in 2015 on the range of health workers who can provide safe abortion care and manage non-life-threatening complications in the first ( $\leq 12$  weeks) and second trimester (13–28 weeks) in both high- and low-resource settings [6]. The guideline does not recommend that pharmacy workers and lay health workers independently provide MA because there is currently insufficient evidence. However, when appropriately trained, these categories of health workers can, as shown through rigorous research, assess eligibility for medical abortion, administer the medication, manage the process and common side-effects independently, and assess completion of the abortion and the need for any clinic-based follow-up, for women in the first trimester of pregnancy [7–10].

In Nepal, national guidelines published by the Ministry of Health in 2009 allowed independent provision of MA by skilled birth attendants and trained auxiliary nurse-midwives (ANMs) up to 9 weeks gestation. Off-label or over-the-counter sale of MA tablets at pharmacy shops was not permitted. Despite these restrictions, various brands of registered and unregistered MA drugs are sold by pharmacy shops. Ensuring that women seeking abortion advice from pharmacy workers receive effective care remains an important challenge in Nepal.

However, trained pharmacists and pharmacy workers have successfully delivered care related to sexually transmitted infections, contraception and emergency contraception. Their success is due to their ability to facilitate rapid access to medications, supplies, information and advice, while maintaining client confidentiality [9–10].

Harm reduction is an evidence-based public health and human rights approach that prioritizes strategies to preserve health in situations where policy and practice prohibit and drive common activities underground [11]. In the context of the present study, the aim of a harm reduction strategy is to stop pharmacy workers from dispensing ineffective and unsafe medications for abortion or dispensing incorrect doses of MA pills. We hypothesized that training pharmacy workers in correct use of MA, including assessment of number of weeks of pregnancy, use of a urine pregnancy test, providing correct and complete information on regimens and effective routes of administration, and when to see a trained provider for follow-up care in case of incomplete abortion or

signs and symptoms of complications, would lead to a decline in incorrect use of MA and other ineffective drugs. Through this process women's safety would be improved and abortion-related complications would decrease.

A previous study carried out by our group, published in 2014 [12], demonstrated that pharmacy workers trained to provide MA using this harm reduction approach had increased their knowledge of recommended regimens, effective routes of administration, the recommended time gap between the two types of pill, and how to recognize a complete abortion. This, in turn, led to a decline in the incorrect provision of MA tablets and other ineffective drugs by pharmacy workers and increased referrals to safe abortion clinics when follow-up care was needed. The trained pharmacy workers reported that of 5594 women receiving MA drugs from them, only 18 women (0.03%) had had an incomplete abortion [12]. However, the study had not followed up the women themselves who had obtained MA pills from the pharmacy workers. Because an increasing number of women are getting MA from pharmacy shops, we felt it was imperative to carry out a prospective study that would follow up women clients.

The operations research reported in this paper aimed to fill this important data gap, studying the effectiveness of training of pharmacy workers who had not had training previously (Education Group 2 — hereafter GROUP 2) and also studying client compliance and satisfaction, and safety and effectiveness of MA as reported by the women. The results were then compared with those among women who had obtained MA from pharmacy workers in an adjoining district (Education Group 1 — hereafter GROUP 1), who had had similar training a few years before. The findings of this study would contribute to reforming policies aimed at expanding MA services in the private sector through trained pharmacy workers and to ensure greater safety, efficacy and acceptability of MA in Nepal.

## 2. Materials and methods

### 2.1. Study population

This was an operations research study conducted in Makwanpur and Chitwan districts using a non-inferiority design. This design was aimed to show that the effect of a new treatment is as good as, or better than that of an active comparator. We selected the two groups of pharmacy workers on the basis of geographical proximity between them (in neighboring districts). We trained the group of pharmacy workers in Makwanpur district to provide medical abortion (GROUP 2) safely and effectively. We compared the outcomes for women who obtained MA pills from them, our study participants, with the outcomes for women who had obtained MA pills from a group of pharmacy workers in Chitwan district (GROUP 1), who had received similar training a few years before. This is the first study to compare outcomes of MA use outside the healthcare system.

Makwanpur is a relatively small, hilly district (population 0.42 million) with a small urban population (25.6%). The

pharmacy workers of this district (GROUP 2) did not have previous exposure to MA harm reduction training, while pharmacy workers in Chitwan district had (GROUP 1). Chitwan is a relatively large district (population 0.58 million) with a large urban population (46.2%). The pharmacy workers in Chitwan had received harm reduction training from a non-governmental organization (NGO) in 2010. This district has two large public hospitals and 16 private hospitals that provide safe abortion services. Moreover, Chitwan was one of the first six districts where MA was introduced in a pilot program through government-run and non-government-run health facilities and scaled up in later years.

We purposively selected 42 pharmacy shops in each district that provided MA pills over the counter to women and were willing to participate in the study and allow our female researchers access to their MA clients (our study participants) for two rounds of interviews. In a pre-intervention baseline survey, we created a sampling framework for the selection of pharmacy shops for inclusion in the study.

We trained the pharmacy workers in GROUP 2 in safe use of MA, including correct assessment of gestational age based on last menstrual period (LMP); correct dose and regimen and effective routes of administration for misoprostol; how to recognize signs, symptoms and possible adverse events after MA intake; and timely referral to a safe abortion clinic in case of complications. We also instructed them in the importance of follow-up visits as part of the study, including orientation on how to coach MA clients about completing the study's self-assessment card.

We asked the pharmacy workers in both Groups to record basic information about all the women to whom they provided MA tablets. That information included: the woman's age, educational attainment, marital status, number of previous pregnancies, date of LMP and number of weeks of current pregnancy, method used to confirm gestational age, brand name of MA tablets dispensed to the woman, and date of next follow-up visit. We asked the pharmacy workers to obtain preliminary informed consent from the women for participation in the study while filling in the forms. Women who agreed to participate in the study were given a follow-up visit date (normally 10–14 days after taking mifepristone). The pharmacy workers took down the women's personal phone numbers to remind them of the follow-up visit and provided them with the self-assessment card designed especially for this study and the pharmacy shop's contact phone number.

The 42 pharmacy workers in each of the two groups came from different professional backgrounds and training. We delineated them into two broad categories — those with health backgrounds and those without health backgrounds. The first category included health assistants (HA), ANM, auxiliary health workers (AHW), and community medicine assistants (CMA), who were “paramedics”. Those without health backgrounds included individuals with a formal Bachelors' degree or Diploma in Pharma-

cology (B. Pharma and D. Pharma) and lay individuals who had acquired orientation training from the Department of Drug Administration (DDA) for dispensing medicines in pharmacy outlets.

The 992 women who agreed to participate had received MA tablets from the pharmacy workers and were interviewed by 12 female Nepali researchers, who were trained to conduct two rounds of individual interviews with the women. The first round of interviews was conducted when the women came for a follow-up visit to the pharmacy shop between days 10 and 14. The second round of interviews was scheduled at the pharmacy shop on the 30th day after mifepristone intake. However, all the women were advised to visit the nearest health facility if they experienced adverse signs and symptoms other than those associated with MA and indicated in the brochure they were given with supporting information.

The Family Health Division, Ministry of Health, Government of Nepal gave permission to conduct this study, and the Nepal Health Research Council gave ethical approval (Study Approval Reg. No. 275/2014; 16 January 2015).

## 2.2. Measures

The primary endpoint measured and compared in this study was complete abortion within 30 days of MA use. The first interview with women aimed to assess the efficacy of MA (self-reported complete abortion) and safety (absence of any adverse event — e.g., heavy bleeding, fever, diarrhea — with MA use). The second interview was to re-confirm complete abortion and assess client satisfaction levels. Any complications were noted at both interviews. To determine complete abortion, we used women's response about passage of the products of conception with or without vaginal bleeding, bleeding without the need for manual vacuum aspiration (MVA) or repeated doses of misoprostol, and cessation of abdominal cramps and pain. Only pharmacy workers with an ANM background did a clinical examination or ultrasound. We defined incomplete abortion as continuing bleeding and retention of the products of conception within 30 days of mifepristone intake. We defined failed abortion as no bleeding, no abdominal cramps, and no expulsion of the products of conception within 30 days of mifepristone intake. We used a Lickert Scale (one to four point rating scales — highly satisfied, satisfied, not satisfied and not satisfied at all) to determine level of satisfaction with MA use. We combined highly satisfied and satisfied and defined this as “satisfied”. Similarly, not satisfied and not satisfied at all were combined and defined as “not satisfied”.

## 2.3. Analysis

To assess the treatment efficacy and safety of the harm reduction training on safety of MA use by the women, we considered three parameters: (1) percentage of women reporting complete abortion; (2) percentage of women

reporting incomplete abortion who had MVA elsewhere or took a repeat dose(s) of misoprostol from another health provider; and (3) percentage reporting continuing pregnancy. We compared these parameters between the two pharmacy worker groups, and also by the professional backgrounds of the pharmacy workers. The primary outcome of our non-inferiority analysis was the non-inferior efficacy of the medical abortion provided by pharmacy workers of GROUP 2. We had set the confidence level of CI to 95%, corresponding to a 2.5% one-sided significance level. We used a Pearson  $\chi^2$  test to compare the proportions of complete abortion between the two groups and by the professional background of the pharmacy workers.

### 3. Results

From mid-March to mid-September 2015, 1205 women sought abortion advice from the pharmacy shops in the two groups. Of these, 1121 women (93%) received MA tablets, and 1100 of them agreed to participate in the study upon the pharmacy workers' request. Only 21 women refused to be interviewed. A total of 992 women (478 in GROUP 2 and 514 in GROUP 1) returned to the pharmacy shops 10–14 days after taking mifepristone were interviewed by the researchers (first interview). Of these, 947 women (440 women from GROUP 2 and 507 from GROUP 1) returned to the pharmacy shop on

their 30th day of mifepristone in-take for the second round of interview (Fig. 1).

The 108 women who were lost to follow-up for the first interview, 102 were from GROUP 2 (Makwanpur district), which was one of the worst affected districts in the earthquakes of April 29 and May 12, 2015. Seven pharmacy workers involved in the study had to close down their pharmacy shops due to the devastation of the earthquakes. The 108 women lost to follow-up were, on average, less educated than those who came for the interview ( $p \leq .05$ ), but there was no significant difference in terms of median age, marital status or average number of pregnancies.

The background characteristics of the women in GROUP 2 (478 women) and Group 1 (514 women) were broadly similar (Table 1). On average, the women were 27 years old (SD 4.931 and 4.697 for GROUP 2 and GROUP 1 respectively) and nearly all of them were married (96% in GROUP 2 and 98% in GROUP 1). A quarter of the women in GROUP 2 had no formal education (27%) while in GROUP 1 this was 6%, while fewer women in GROUP 2 had secondary and higher education (55%) than in GROUP 1 (78.8%) ( $p \leq .001$ ). The average number of pregnancies varied marginally between the groups (2.8 pregnancies in GROUP 2 vs. 2.6 in GROUP 1,  $p \leq .01$ ).

The majority of the women (70%) were  $\leq 6$  weeks pregnant when they sought MA. Only 3% of those who received MA tablets were  $\geq 10$  weeks pregnant.

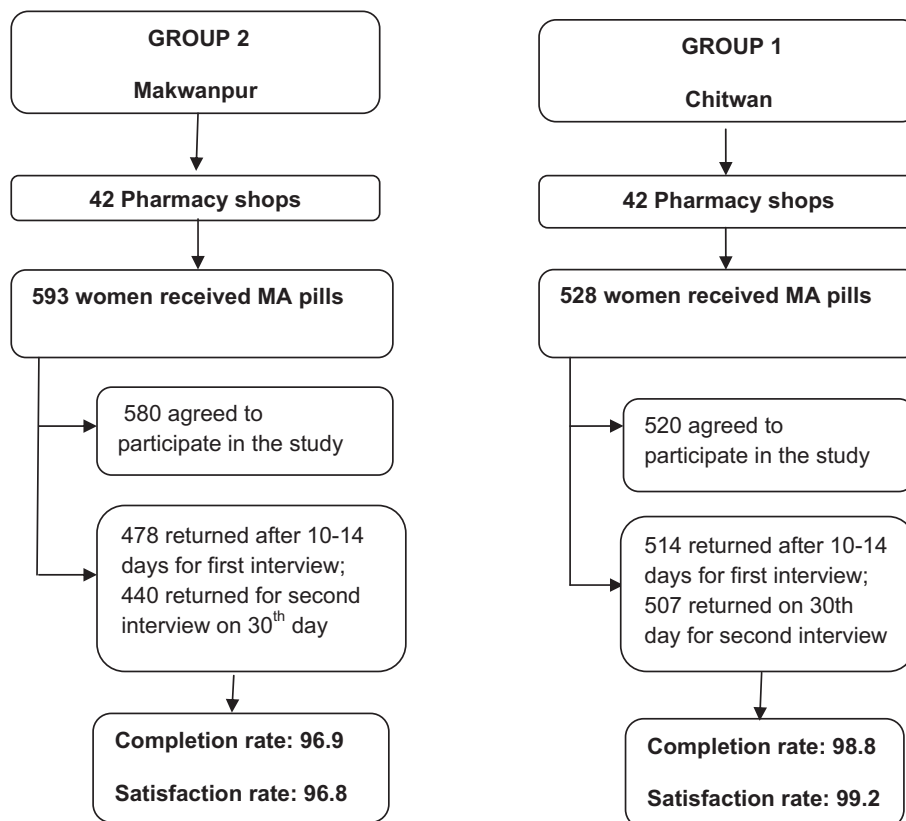


Fig. 1. Outcome of the MA pills provided by pharmacy workers to women from two comparison groups.



Table 1  
Background characteristics of the participating women.

Characteristics	GROUP 2 (Makwanpur) (N=478)	Percent.	GROUP 1 (Chitwan) (N=514)	Percent.
<b>Age</b>				
≤19	12	2.5	9	1.8
20–29	312	65.3	352	68.5
30–39	148	31.0	145	28.2
≥ 40	6	1.3	8	1.6
Mean (SD)	27.29 (4.931)		27.08 (4.697)	
Median	27.00		27.00	
<b>Marital status</b>				
Married	460	96.2	502	97.7
Separated/divorced/ widowed	2	0.4	3	0.6
Unmarried	16	3.3	9	1.8
<b>Education (***)</b>				
Never attended school/Non-formal education	127	26.6	30	5.8
Primary	88	18.4	79	15.4
Secondary	174	36.4	261	50.8
Higher	89	18.6	144	28.0
<b>Number of pregnancies including current pregnancy (***)</b>				
1	71	14.9	59	11.5
2	141	29.5	211	41.1
3	136	28.5	151	29.4
4 or more	130	27.2	93	18.1
Mean (SD)	2.84 (1.338)		2.60 (1.043)	
<b>Previous induced abortions</b>				
0	368	77.0	393	76.5
1	88	18.4	103	20.0
2 or more	22	4.6	18	3.5
Mean (SD)	0.29(0.612)		0.27(0.526)	
<b>Gestational age based on LMP (weeks) (***)</b>				
Up to 6 weeks	306	64.0	389	75.7
7–9 weeks	156	32.6	114	22.2
10+ weeks	16	3.3	11	2.1
Mean	6.30 (1.424)		5.96 (1.264)	
Median	6.00		6.00	

Note: \*\*\* p<.001.

There were more pharmacy workers with a health background in GROUP 1 (37/42) than in GROUP 2 (33/42) (Table 2). Very few pharmacy workers were women (4 in GROUP 2 and 5 in Group 1). However, there were more female paramedics in GROUP 2 (7) than in GROUP 1 (1).

Of the 478 women interviewed in GROUP 2, 463 (96.9%) reported complete abortion, while 508 (98.8%) of the 514 women in GROUP 1 did so. The risk difference for complete abortion rate between GROUP 1 and GROUP 2 was 3.12 (95% CI=1.22–7.99) (Table 3). In GROUP 2, 15 women (3.1%) reported incomplete abortion as against 6 women (1.2%) in GROUP 1. All the women who reported incomplete abortions had an MVA from a public or NGO clinic. No serious complications or adverse events were

Table 2  
Profile of the participating pharmacy workers.

Professional background	GROUP 2 (Makwanpur)	GROUP 1 (Chitwan)
<b>A. Health Background</b>		
Health Assistant	5	5
Staff Nurse	1	-
Auxiliary Nurse Midwife	3	5
Auxiliary Health Worker	1	3
Community Medicine Assistant	23	24
<b>Total A</b>	<b>33</b>	<b>37</b>
<b>B. Pharmacy &amp; Non-Health Background</b>		
Bachelor in Pharmacology	1	2
Diploma in Pharmacology	2	2
Other category (DDA trained only)	6	1
<b>Total B</b>	<b>9</b>	<b>5</b>
<b>Total (A + B)</b>	<b>42</b>	<b>42</b>

reported by any of the 992 women interviewed, and none of them reported a continuing pregnancy.

We assessed the gestational age, MA regimen and route of administration of misoprostol among the 21 women (15 in GROUP 2 and 6 in GROUP 1) who had incomplete abortions, and the brand of tablets they used (data not shown). With the exception of one woman, the gestational age was ≤7 weeks for 14 of the woman and ≤9 weeks in the other 7 women at the time of taking the MA tablets. With the misoprostol tablets, 12 women had taken them orally; 5 women had used them vaginally and the remaining 4 women had used them sublingually. There was no difference in the recommended route of misoprostol administration by background of the pharmacy workers. The MA tablets used by 8 of 15 women in GROUP 2 and 5 of 6 women in GROUP 1 were brands registered with the government, while the remaining 8 women, half in each group, were given 8 different unregistered brands of MA tablets in combi-packs.

On the supply side, there was no uniformity across the pharmacy workers as regards which brands of MA tablets they sold to the women. Because the prices of different brands varied considerably at the time of the study — from NPR 500 to 1000 (US \$4.70–9.40) per combi-pack of mifepristone and misoprostol — clients were given a choice based on price. These prices were in fact comparable to the MA services fee charged at public sector health facilities.

Overall, 98% who returned at the pharmacy for second round of interview expressed satisfaction with MA use (73% satisfied and 25% highly satisfied). There was not much difference in the satisfaction levels between the two groups, though the percentage of women who said they were highly satisfied was higher in GROUP 2 (29%) than in GROUP 1 (21%) (p≤.001). Almost all participating women in both groups (98% in GROUP 2 and 100% in GROUP 1) said they would recommend the pharmacy shop they had visited for MA to a friend or relative (Table 4).

Table 3  
Outcomes of medical abortion use.

	GROUP 2 (Makwanpur)	GROUP 1 (Chitwan)	Proportional difference of complete abortion at 95% CI	Risk difference at 95% CI
Number of women	478	514		
Complete abortion	463 (96.9%)	508 (98.8%)	2.39 (0.49 to 4.29)	3.12 (1.22 to 7.99)
Incomplete abortion	15 (3.1%)	6 (1.2%)		
Continuing pregnancy	0	0		

#### 4. Discussion

This is the first-ever study conducted with MA clients of pharmacy workers in Nepal that we know of. In view of the illegality of over-the-counter sale of MA tablets by pharmacy shops, the research team made every effort to gain pharmacy workers' confidence and consent to interview their clients. To protect the privacy and confidentiality of the women clients, the pharmacy workers agreed to obtain initial informed consent for the women's participation in the study. The researchers also made diligent efforts to minimize loss to follow-up by paying for the phone calls to remind the women of the date of follow-up visits and also paid for the cost of transportation of the women who came to the pharmacy shops for the interviews.

This study shows that harm reduction training provided pharmacy workers in two districts of Nepal with correct information on MA and that they were able to dispense MA tablets successfully for safe and effective use by women [12]. The study also shows the extent of safety and effectiveness of MA use among the women who obtained MA tablets from the trained pharmacy workers, based on interviews with the women. One limitation is that post-abortion contraception was not included in the harm reduction training and is therefore not discussed in this paper. We do, though, consider this an important gap that needs to be addressed in future interven-

tions. Another limitation of this study is that our active comparator group was not the health system standard (that is, a comparison with traditional clinic providers). However, our results do compare favorably with a multi-center randomized controlled equivalence trial conducted in five hospitals in Nepal that found that the provision of medical abortion up to 9 weeks gestation by mid-level healthcare providers (nurses) and doctors was similar in safety and effectiveness [2].

The results in both groups of women demonstrated very high rates of complete abortion. The fact that most women were  $\leq 6$  weeks pregnant when they sought MA tablets is also noteworthy in this regard.

The GROUP 1 pharmacy workers had been providing MA for a longer period of time after being trained; they also included a relatively larger proportion of health worker cadres than GROUP 2. On the other hand, a significantly higher proportion of women in GROUP 2 expressed high satisfaction with MA use, which may have been due to the fact their pharmacy workers, being recently trained, gave more thorough information, e.g. on what to expect, pain management, and so on. What is important, however, is that the positive results of training were manifested in both groups and were shown to be continuing among the women in GROUP 1 several years after their training.

#### 5. Conclusions

We conclude that pharmacy workers in Nepal, if adequately trained, can safely and effectively dispense MA to women with or without a prescription, based on the high level of complete abortion, absence of serious complications, attendance for follow-up care when needed, high client satisfaction with MA use and high acceptability among women of pharmacy workers as a source of MA.

The harm reduction training for pharmacy workers provided in this study was highly successful. The results also show that pharmacy workers who had been trained several years before had retained enough knowledge to continue to dispense MA safely and with a high efficacy rate and satisfaction among women.

The role of pharmacy workers as providers of MA needs to be recognized by the government of Nepal and policies formulated to allow pharmacy workers to give information about and provide MA tablets to women in the first trimester of pregnancy.

Table 4  
Extent of satisfaction with medical abortion received from pharmacy workers.

	GROUP 2 (Makwanpur) (N)	Percent.	GROUP 1 (Chitwan) (N)	Percent.	Total (N)	Percent.
<b>How satisfied are you with MA use?</b>						
Highly satisfied	129	29.3***	105	20.7	234	24.7
Satisfied	297	67.5	398	78.5	695	73.4
Not satisfied	10	2.3	4	0.8	14	1.5
Can't say	4	0.9	-	-	4	0.4
<b>Would you recommend friend/relative to this pharmacy shop for MA?</b>						
Yes	430	97.7	505	99.6	936	98.7
No	10	2.3	2	0.4	12	1.3
<b>Total</b>	<b>440</b>	<b>100.0</b>	<b>507</b>	<b>100.0</b>	<b>947</b>	<b>100.0</b>

Note: \*\*\* p<.001.

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