

Hourly Low-Dose Oral Misoprostol Solution for Induction of Labour at Term: A Prospective Observational Study from a Pakistan

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Abstract:

Objectives: To evaluate the effectiveness and short-term safety of an hourly 20 µg oral misoprostol solution protocol for induction of labour (IOL) in primigravid term pregnancies at a Pakistani tertiary center.

Study design and setting: Prospective observational study conducted in the Department of Gynecology & Obstetrics, Sadiq Abbasi Hospital / Quaid-e-Azam Medical College, Bahawalpur, from 21-Nov-2024 to 21-May-2025.

Methodology: Primigravida with singleton, cephalic, 37–42-week gestations, Bishop score >5, and reactive CTG were enrolled; women with prior uterine surgery or other contraindications to vaginal birth were excluded. Misoprostol 200 µg was dissolved in 200 mL of water; 20 mL (20 µg) was given orally every hour until adequate uterine activity or a maximum of 10 doses. Oxytocin was started if contractions became inadequate after active labour onset.

Results: One hundred women were included (mean age 27.20 ± 3.62 y; mean gestation 38.65 ± 1.51 weeks; mean estimated fetal weight 2511.05 ± 265.42 g). Mean pre-induction Bishop score 6.32 ± 0.98 improved to 7.43 ± 1.65 at 6 h. The mean induction-to-delivery interval was 12.43 ± 3.21 h; the mean misoprostol doses were 5.52 ± 1.62 . Vaginal birth within 24 h occurred in 79/100 (79%; 95% CI 71–87). Oxytocin augmentation was required in 28% and meconium-stained liquor occurred in 18%.

Conclusion: Hourly 20 µg oral misoprostol solution achieved high 24-h vaginal-delivery rates with generally reassuring short-term outcomes within recorded parameters in primigravid women at term in this tertiary-care Pakistani cohort. Larger comparative studies are warranted.

Keywords: Cesarean Section, Labor, Induced, Misoprostol, Pakistan, Pregnancy, Term

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INTRODUCTION:

Induction of labour (IOL) is undertaken in approximately 20–30% of pregnancies worldwide to reduce maternal or fetal risks when continuing the pregnancy is no longer

beneficial.¹ Because the likelihood of vaginal birth after IOL depends strongly on cervical favorability, the Bishop score remains an important predictor that guides method selection.²

Multiple pharmacologic and mechanical approaches to IOL are available, including prostaglandins (dinoprostone, misoprostol) administered orally, vaginally, or buccally/sublingually; transcervical balloon catheters; amniotomy; oxytocin; and various combinations.^{3,4} In resource-constrained settings, agents that are inexpensive, heat-stable, and easy to administer are especially valuable.^{1,3} Misoprostol, a synthetic prostaglandin E1 analogue, meets many of these criteria, and major guideline bodies endorse its judicious use for IOL in appropriately selected women, typically excluding those with a prior uterine scar, and with adequate fetal and uterine monitoring.^{4,5} Recent international guidelines from the World Health Organization (WHO) and American College of Obstetricians and Gynecologists (ACOG) explicitly recognize oral misoprostol as an acceptable option for cervical ripening/induction with appropriate monitoring and locally approved protocols.^{6,7}

The oral route of misoprostol offers practical advantages for both patients and health systems. Compared with vaginal

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administration, oral dosing may reduce the need for repeated vaginal examinations, facilitate ambulation and mobility, and allow more responsive titration of dose according to uterine activity and fetal status. In addition, pharmacokinetic and protocol data support re-dosing at approximately 1–2-hour intervals to achieve steady stimulation without excessive peaks in uterine activity. Accurate micro-dosing can be achieved by dissolving a 200- μ g tablet in 200 mL of water to yield a 1 μ g/mL solution; measured aliquots permit delivery of very low doses with minimal wastage and consistent preparation at the bedside.⁴ Contemporary dosing aids from the International Federation of Gynecology and Obstetrics (FIGO) also summarize low-dose oral regimens and emphasize safety considerations (for example, avoiding buccal/sublingual routes for viable pregnancies).⁸

Evidence supporting low-dose oral misoprostol includes prospective cohort studies and randomized trials conducted across diverse populations and clinical settings. The PROBAAT-II multicenter randomized controlled trial found that oral misoprostol was comparable to a Foley catheter in terms of effectiveness and safety during term inductions, reinforcing its role as a viable cervical ripening and induction strategy.⁵ Beyond device comparators, solution-based regimens have been evaluated: an Indian series using an oral misoprostol solution reported vaginal birth within 24 hours in roughly 80% of cases, suggesting timely efficacy with acceptable safety.⁹ Furthermore, randomized comparisons of hourly titrated versus two-hourly static oral misoprostol regimens have indicated favorable outcomes with carefully titrated protocols, supporting the biological plausibility and clinical utility of small, repeated oral doses.^{10,11} A 2021 Cochrane Review focused on low-dose oral regimens (initial dose 250 μ g) and concluded that oral misoprostol probably improves key outcomes versus several comparators while reducing hyperstimulation compared with vaginal misoprostol.¹²

Despite this growing international experience, oral misoprostol solution has not been widely adopted across many Pakistani labour wards. Potential barriers include variability in local protocols, concerns about standardization of solution preparation, staffing and monitoring requirements, and limited availability of local outcomes data to guide context-specific implementation.^{3,4} In settings where cesarean section capacity is constrained and the burden of referral is high, a simple, low-dose oral protocol that achieves high rates of timely vaginal birth while maintaining safety would be valuable for patients and providers alike.^{1,10} Generating local evidence is therefore essential to address uncertainties about effectiveness, dosing logistics, and near-term maternal and neonatal outcomes within our practice environment.

The objective of the study was to evaluate, in a tertiary-care Pakistani setting, the effectiveness and short-term safety of an hourly 20 μ g oral misoprostol solution protocol for the induction of labour in primigravid term pregnancies.

Specifically, we assessed the rate of vaginal birth within 24 hours as the primary outcome, and we described the induction-to-delivery interval, need for oxytocin augmentation, and selected maternal and neonatal events as secondary outcomes.

METHODOLOGY:

A prospective observational study was conducted in the Department of Obstetrics & Gynecology at Sadiq Abbassi Hospital/Quaid-e-Azam Medical College (QAMC), Bahawalpur, Pakistan. The study period was six months from 21 November 2024 to 21 May 2025. Consecutive eligible women presenting to the labour ward during this period were invited to participate. Protocol approval was granted by the Institutional Review Board, QAMC (ERC No.: 310/DME/QMC Bahawalpur). The study complied with the Declaration of Helsinki and ICH-GCP; participation was voluntary, and patients could withdraw at any time without impact on care. Written informed consent was obtained from all participants before enrollment. No procedures commenced before consent was signed and witnessed.

Eligibility was predefined. Primigravid women of any age with singleton, cephalic pregnancies at 37+0 to 42+0 weeks were included. We required a Bishop score >5 at presentation with a reactive cardiotocograph/non-stress test, consistent with contemporary guidance that recommends misoprostol use in appropriately selected term, singleton, vertex pregnancies with reassuring fetal status.^{6–8,12} Exclusions comprised any contraindication to vaginal birth (placenta previa, placenta accreta spectrum, antepartum hemorrhage of uncertain origin, non-cephalic or unstable lie, multiple pregnancy, estimated fetal weight >4 kg, prior uterine surgery including caesarean, myomectomy, or metroplasty), non-reassuring baseline CTG, hypersensitivity to prostaglandins, or refusal of consent. Exclusion of a prior uterine scar and non-reassuring fetal status follows WHO, ACOG, and FIGO recommendations for safe use of oral misoprostol in viable pregnancies.^{6–8,12} After consent, prespecified variables were recorded on a case record form: maternal age, gestational age, booking status, estimated fetal weight, and baseline Bishop score. General, abdominal, and pelvic examinations were performed by a consultant obstetrician. To minimize inter-observer variation, the same examiner reassessed the Bishop score at 6 hours when feasible. Ultrasound was used to confirm dating, amniotic fluid, placental location, and estimated fetal weight. Induction was carried out using an oral misoprostol solution at 1 μ g/mL. A 200 μ g tablet was dissolved in 200 mL of drinking water, and the bottle was inverted before each withdrawal. A dose of 20 mL (20 μ g) orally every hour was administered until adequate uterine activity occurred or a maximum of 10 doses (200 μ g total) was reached. The prepared solution was stored at room temperature and discarded after 24 hours. Adequate uterine activity was defined as ≥ 3 contractions per 10 minutes, each

=30 seconds. The next dose was withheld for tachysystole (>5 contractions per 10 minutes), any prolonged contraction (>2 minutes), or fetal heart rate (FHR) abnormalities. Active labour was defined as regular painful contractions with cervical dilatation =5 cm (local protocol). No further misoprostol was given once active labour began. Oxytocin augmentation was initiated after active labour onset if contractions fell below 3 per 10 minutes (lasting <20 seconds) or if cervical progress was inadequate for 4 hours. The infusion was started at 2 mU/min and increased every 30 minutes to a maximum of 20 mU/min, titrated to uterine response. During misoprostol administration, intermittent CTG was used with 15–20 minutes of monitoring after each dose. This approach aligns with World Health Organization recommendations for low-risk term inductions in settings where continuous cardiotocography is not feasible, provided that facilities for escalation to continuous monitoring and emergency operative delivery are available. Thereafter, monitoring followed hospital protocol: intermittent auscultation every 30 minutes in the latent phase and continuous monitoring in active labour. Maternal pulse, blood pressure, temperature, and uterine activity were charted hourly on the Labour Care Guide. Decisions for lower-segment caesarean section (LSCS) were made by the consultant obstetrician. Indications included non-reassuring FHR or suspected fetal compromise, failed induction (no active labour after 10 doses and/or 24 hours from first dose), arrest disorders in active labour, and other emergencies (e.g., cord prolapse, severe bradycardia). All indications were recorded.

The primary outcome was vaginal birth within 24 hours of the first misoprostol dose. Secondary outcomes were total vaginal birth rate (any interval), induction-to-delivery interval (hours), change in Bishop score from baseline to 6 hours, number of misoprostol doses, need for oxytocin augmentation, mode of delivery, maternal adverse events (tachysystole; hyperstimulation defined as tachysystole with FHR change; postpartum haemorrhage >1000 mL or transfusion; maternal fever =38 °C), and fetal/neonatal outcomes (meconium-stained liquor; Apgar at 1 and 5 minutes; Apgar <7 at 5 minutes; NICU admission; perinatal death).

The sample size was calculated using the single-proportion sample size formula $n = Z^2 \cdot P \cdot (1-P)/d^2$, where $P = 0.805$ for vaginal birth =24 h, $Z = 1.96$ (95% confidence), $d = 0.08$, and $Q = 1-P = 0.195$, giving $n = 93.4$.⁹ A target of 100 participants was set to allow for attrition and protocol deviations. Data were recorded contemporaneously on paper forms and double-entered into a password-protected SPSS v24 database. Weekly range and logic checks were performed. Normality was assessed with the Shapiro–Wilk. Normally distributed continuous variables are reported as mean \pm SD; skewed variables as median (IQR). Categorical variables are presented as n (%) with 95% confidence intervals for

key proportions. The primary outcome (?24-hour vaginal birth vs not) was compared across prespecified subgroups (age category, gestational age category, estimated fetal weight category, oxytocin augmentation, meconium) using χ^2 or Fisher's exact tests. Continuous variables were compared using a t-test or Mann–Whitney U as appropriate. A two-sided $p < 0.05$ was considered significant. Analyses followed an intention-to-treat approach, with all enrolled women included. Missing data were handled by complete-case analysis. Outliers were verified against source records before the database lock. This was an observational, non-randomized, unblinded study. Randomization, allocation concealment, and masking were not applicable.

RESULTS:

One hundred eligible primigravid women were enrolled during the study period; all received the protocol and were followed through delivery. There were no post-enrolment exclusions and no losses to follow-up.

Participant age ranged 18–40 years (mean 27.20 ± 3.62); 72% were 18–30 years. Mean gestational age at induction was 38.65 ± 1.51 weeks (68% at 37–39 weeks; 32% at 40–42 weeks). The mean estimated fetal weight (EFW) at assessment was 2511.05 ± 265.42 g; 52% had EFW =2500 g. Table 1 shows the baseline maternal and pregnancy characteristics of the study participants. Baseline Bishop score averaged 6.32 ± 0.98 and increased to 7.43 ± 1.65 at 6 h after the first misoprostol dose (mean change +3.11 points). Women received a mean of 5.52 ± 1.62 hourly 20- μ g misoprostol doses before the protocol was stopped for adequate uterine activity or progression to active labour. The mean induction-to-delivery interval was 12.43 ± 3.21 h. Table 2 shows the labour process measures, including changes in Bishop score, induction-to-delivery interval, and misoprostol doses administered. Oxytocin augmentation after misoprostol was required in 28% of women. Meconium-stained liquor was documented in 18%. Mean 1- and 5-min Apgar scores were 8.32 ± 1.23 and 8.96 ± 1.02 , respectively. Additional maternal complications (tachysystole, postpartum hemorrhage) and neonatal outcomes (NICU admission, Apgar <7) were not systematically recorded in the dataset available for analysis. Table 3 shows the maternal and neonatal outcomes following induction with oral misoprostol solution. Prespecified maternal adverse events, including tachysystole, uterine hyperstimulation, postpartum haemorrhage, and neonatal intensive care unit admission, were not systematically recorded in the available dataset and are therefore not reported. Vaginal delivery within 24 h of the first misoprostol dose, the prespecified primary endpoint, occurred in 79 women (79%; 95% CI 71–87%). Twenty-one women (21%; 95% CI 13–30%) underwent caesarean delivery (LSCS) under protocol criteria (failure to deliver within 24 h and/or clinical indications). No instrumental vaginal deliveries were recorded separately. Table 4 presents the mode of delivery and the primary

outcome, along with 95% confidence intervals. Table 5 shows the distribution of indications for LSCS among the 21 patients who underwent caesarean delivery. In this prospective cohort of 100 primigravid term women induced with an hourly 20- μ g oral misoprostol solution, 79% (95% CI 71–87) achieved vaginal birth within 24 hours, and 21% (95% CI 13–30) delivered by caesarean section. The mean induction-to-delivery interval was 12.43 h, the mean number of misoprostol doses was 5.52, and the Bishop score improved from 6.32 at baseline to 7.43 at 6 hours. Oxytocin augmentation was used in 28%, and meconium-stained liquor occurred in 18%. Neonatal status was generally reassuring (Apgar 1 min 8.32; 5 min 8.96). There were no post-enrolment exclusions or losses to follow-up; some prespecified maternal and neonatal safety endpoints were not systematically recorded.

DISCUSSION:

In this prospective observational cohort of 100 primigravid women at term (37–42 weeks) with unfavorable cervix (baseline Bishop 6.32 \pm 0.98), an hourly 20- μ g oral misoprostol solution regimen achieved vaginal birth within 24 h in 79% of participants. The mean induction-to-delivery interval was 12.43 \pm 3.21 h, the Bishop score improved by around 3 points at 6 h, 28% required oxytocin augmentation

after active labour onset, and meconium-stained liquor was observed in 18%. Neonatal status was reassuring with mean 1- and 5-min Apgar scores of 8.32 \pm 1.23 and 8.96 \pm 1.02, respectively.

Induction of labour is one of the most common procedures being done in labour rooms. Various mechanical and pharmacological methods are used to start labour. Mostly vaginal prostaglandins are licensed for the induction of labour in term pregnancies with a viable fetus in various countries. But these vaginal prostaglandins (PGE2) are expensive, require temperature maintenance, and hence make them inappropriate for poor resource settings in developing countries like ours. Hence pocket-friendly, heat-stable, and freely available options and regimens are required.

Misoprostol is a synthetic analogue of prostaglandin E1, which has gastric and mucosal protective effects. It is widely used in oral form by physicians for patients with acid peptic disease or gastric ulcers. It is also prescribed as a safety agent in people who chronically use painkillers for osteoarthritis or other reasons.¹⁰ Furthermore, misoprostol also exhibits uterotonic properties, i.e., it stimulates the contractions of the smooth muscles of the uterus, hence making it a principal part of the bundle approach to PPH management. It also, on the other hand, contracts smooth

Table 1. Baseline Characteristics (n=100)

Characteristic	Category	N	%	Summary (mean \pm SD)
Maternal age (y)	18–30	72	72.0	27.20 \pm 3.62
	31–40	28	28.0	
Gestational age (weeks)	37–39	68	68.0	38.65 \pm 1.51
	40–42	32	32.0	
Estimated fetal weight (g)	\leq 2500	52	52.0	2511.05 \pm 265.42
	>2500	48	48.0	

Table 2. Labour Process Measures (n=100)

Variable	Mean \pm SD
Bishop score, baseline	6.32 \pm 0.98
Bishop score, 6 h	7.43 \pm 1.65
Induction-to-delivery interval (h)	12.43 \pm 2.21
Misoprostol doses administered	5.52 \pm 1.62
Apgar score, 1 min	8.32 \pm 1.23
Apgar score, 5 min	8.96 \pm 1.02

Table 3. Maternal and Neonatal Outcomes (n=100)

Outcome	N	%	Notes
Maternal			
Oxytocin augmentation	28	28.0	Initiated for inadequate contractions/progress per protocol.
Fetal/neonatal			
Meconium-stained liquor	18	18.0	Any grade.
Apgar 1 min (mean \pm SD)	—	—	8.32 \pm 1.23
Apgar 5 min (mean \pm SD)	—	—	8.96 \pm 1.02

Table 4. Mode of Delivery and Primary Outcome (n=100)

Outcome	N	%	95% CI
Vaginal delivery \leq 24 h			
• Normal	74	74.0	
• Instrumental:	05	5.0	71–87
Forceps	03	3.0	
Vacuum	02	2.0	
Caesarean delivery (LSCS)	21	21.0	13–30

Table 5. Causes of Caesarean Section (n = 21)

Cause	N	%
Non-progress of Labour	8	38.1%
Suspicious CTG	5	23.8%
Fetal Bradycardia	4	19.0%
High head	2	9.5%
Refusal to further trial of labour	2	9.5%

muscles in the myometrium while facilitating the relaxation and effacement of the cervix, resulting in the onset and progress of labour.¹¹ It helps bring changes in cervical consistency, making it soft and favorable for labour. PGE1 in both oral and vaginal routes can be used for IOL and cervical ripening.^{13,14} The dose depends on the parity, period of gestation, and Bishop score. PGE1 oral dosage may cause nausea, abdominal pain, dyspepsia, vomiting, and fever.¹⁰ Additionally, it may cause hyperstimulation, uterine rupture, fetal bradycardia, and fetal demise on the extreme.

Owing to its mechanism on uterine receptors, it is widely used in various routes for the induction of labour and termination of pregnancy for various reasons. It can be given by oral, vaginal, cervical, sublingual, and buccal routes commonly, but its use in the form of oral solution is limited and is still not endorsed by many Hospital protocols. Oral misoprostol solution has a high likelihood of achieving a normal vaginal delivery within 24 hours of IOL. In this study, 79% patients delivered vaginally within 24 hours of induction by oral misoprostol solution. In another study by Deshmukh et al, in India, vaginal delivery was successful in 80.5% women induced with ORAL PGE1 solution. 31% women required oxytocin aid to augment labour and achieve vaginal delivery. 3% of the babies were admitted to the NICU due to meconium, but the Take-home baby rate was 100%.⁹

Antil et al designed a randomized study for IOL. 54 women received titrated oral misoprostol and 52 women received intravenous oxytocin for induction.¹⁵ Induction to delivery interval was shorter in the misoprostol arm than in the oxytocin arm, but the active phase was of the same duration in both groups. In addition, Asokan et al.¹⁶ conducted a comparative study of titrated oral misoprostol solution and oxytocin in 280 term pregnant showed that induction to delivery time was quicker in the misoprostol group 10.1 ± 6.1 than in 12.9 ± 5.4 oxytocin group.

Also, Pambet et al did a randomized controlled trial of 760 term pregnant women, which exhibited similar results in favor of misoprostol solution for IOL.¹⁷ Yenuberi et al an RCT of 83 pregnant women with pre-labour rupture of membranes, reflects that women delivered in 8.4 hours receiving misoprostol as compared to 9.45 hours in the women who received oxytocin for IOL.¹⁸ However, the active phase of labour was the same in both groups. The facts in favor of induction with misoprostol are also favored and supported by homogenous studies like Aalami-Harandi et al a randomized clinical trial of 285 term pregnant women, showing a shorter stretch of labour in the misoprostol group by about 2 hours.¹⁹

Misoprostol in literature is also compared with mechanical methods of IOL. A Dutch multicenter trial published with facts and figures on the safety of misoprostol to the Foley catheter for IOL.⁵ Low-dose misoprostol (25 μ g) when

compared to higher doses (50 μ g) also demonstrates more safety by exhibiting a lower number of instrumental deliveries and fewer babies going to NICU, which supports our personal experience too.²⁰ Aalami-Harandi et al also reinforced the similar promising results of successful IOL with misoprostol leading to normal vaginal delivery when studied in comparison to oxytocin.¹⁹ Similarly, Wasim et al. also discovered a higher proportion of normal vaginal deliveries in the patients receiving oral misoprostol than the dinoprostone given by vaginal route.²¹ Across these comparative studies, oral misoprostol use was associated with lower caesarean section rates compared with published data from alternative induction methods; however, such associations should not be interpreted as causal. Das et al study also suggests more operative deliveries in the oxytocin and dinoprostone groups.^{22,23}

Oral misoprostol, therefore, is an attractive option for induction protocols in labour suites in developing countries because of its safety, feasibility, and efficacy. The dose is minimum, so avoid hyper-stimulation leading to fetal bradycardia, hence minimizing the chances of operative delivery. Furthermore, the use of oral misoprostol solution is more practical because it avoids multiple vaginal examinations for dose repetition only. Multiple vaginal examinations may be uncomfortable and painful for patients, and if done in patients with ruptured membranes, may be a source of infection; and oral route avoids this inconvenience.²⁴ It keeps the patient mobilized, also helping labour.²⁵ Hence, the results of various international studies coincide with our findings, supporting the feasibility of oral misoprostol solution for IOL. However, given the observational design of the present study, these findings should be interpreted as associations rather than evidence of causation.

Strengths of this study include a clearly defined, low-dose hourly protocol; standardized Bishop scoring; intermittent CTG with post-dose monitoring and continuous monitoring in active labour; and complete follow-up for the primary outcome in 100 consecutively enrolled primigravid women. Important limitations must be acknowledged. In addition to the absence of a concurrent control group and potential confounding from clinician-directed oxytocin augmentation in 28% of participants, several prespecified maternal and neonatal safety outcomes—including tachysystole, uterine hyperstimulation, postpartum haemorrhage, and NICU admission—were not systematically captured. This incomplete safety ascertainment limits the strength of conclusions regarding comparative safety and underscores the need for cautious interpretation of reassuring neonatal findings. The single-center design may also limit generalizability beyond similar resource-constrained tertiary units.

Where prostaglandins or mechanical methods are hard to maintain, a 20 μ g hourly oral misoprostol solution, with strict

monitoring and clear stopping rules, may improve access to timely induction and reduce unplanned C-sections in low-resource settings. Guidelines (WHO, FIGO) support such adapted protocols when safety measures (fetal monitoring, emergency C-section capacity) exist.

Studies should compare hourly versus 2-hourly dosing and misoprostol versus alternatives (oxytocin, Foley catheter, dinoprostone), with a safety and cost analysis. Cluster trials or stepped-wedge designs could assess real-world use in South Asian public hospitals. Existing trial data (Iran, Kenya, U.S.) support feasibility and sample-size planning.

This single-center, prospective observational design lacked a concurrent control group; clinician-directed oxytocin augmentation in 28% of participants may have introduced confounding; the study was not powered for infrequent safety endpoints; capture of some prespecified maternal adverse events was incomplete; and external generalizability may be limited to comparable resource-constrained tertiary units.

CONCLUSION:

Hourly low-dose (20 µg) oral misoprostol for induction of labour at term achieved a 79% vaginal birth rate within 24 hours in our primigravid cohort, with generally reassuring short-term maternal and neonatal outcomes. The regimen appears feasible in this setting; however, larger comparative studies with comprehensive safety monitoring are needed before wider adoption.

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Authors Contribution:

Saba Nadeem: Concept & Design of study, revisiting critically, data analysis, final approval of version
Iqra Aslam: Drafting, Revisiting critically, data collection and analysis
Samreen Akram: Drafting, literature search & references, data collection and analysis
Salma Jabeen: Drafting, revisiting critically, data collection and analysis
Irum Manzoor: Drafting, revisiting critically, data collection and analysis.

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