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Adverse Drug Reactions Associated with Misoprostol Use in Medical Termination of Pregnancy: A Retrospective Observational Study of 110 Cases

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Abstract

Background. Misoprostol is a prostaglandin E1 analogue widely used in medical abortion. Gastrointestinal and gynecological symptoms are recognized after misoprostol exposure, while other clinical events may occur but may not be causally attributable to the medicine.

Objective. To evaluate the pattern and frequency of adverse drug reactions and other reported adverse events associated with misoprostol use in medical termination of pregnancy.

Methods. A retrospective observational analysis was performed using 110 clinical case records collected during an eight-month period from January to August 2014. The original dissertation described records from maternity and obstetric settings in Hyderabad, including Apple Hospital, Yakutpura, and Durgabai Deshmukh Hospital, Nallakunta. The records were reviewed for demographic and clinical information, treatment exposure, and reported adverse events. Misoprostol 200 µg was reported by the investigator as being administered by oral or vaginal route. Data were summarized using frequencies and percentages.

Results. Of 110 records, 52 (47.27%) had no adverse drug reaction documented and 58 (52.73%) had at least one reported adverse event. Gastrointestinal effects were categorized in 15 records (13.64%), menstrual/gynecological disorders in 18 (16.36%), and other reported events in 25 (22.73%). Diarrhoea was the most frequently reported gastrointestinal event (8; 7.27% of all records), while spotting was the most frequent gynecological event (7; 6.36%). Because individual records could contain more than one event, event-specific frequencies were not interpreted as independent patient counts.

Conclusion. The retrospective dataset demonstrates a range of adverse events documented following misoprostol exposure, with gastrointestinal and gynecological events representing prominent categories. The findings should not

be interpreted as proof of causality for every reported event. Prospective studies using standardized exposure documentation and formal causality assessment are required to better characterize misoprostol-associated safety outcomes.

Keywords: misoprostol; medical termination of pregnancy; adverse drug reactions; adverse events; pharmacovigilance; drug safety; retrospective observational study

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