The quality of medicines for the prevention and management of hypertensive disorders of pregnancy: a systematic review

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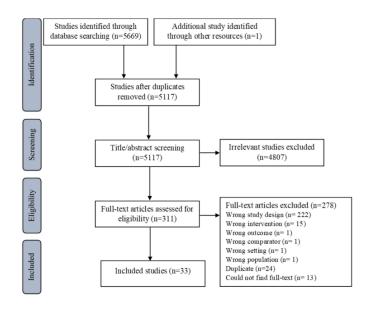
Abstract

Background There is evidence to suggest that many medicines commonly used for pregnant women for the management of hypertensive disorders of pregnancy are poor quality. Objective To review the available studies systematically reporting medicine quality, routinely used in the prevention and management of hypertensive disorders of pregnancy. Search strategy We searched five electronic databases- Ovid MEDLINE, EMBASE, CINAHL, ProQuest and Cochrane Library, without year or language limitations. Selection criteria Studies reporting on quality parameters of nine medicines - magnesium sulphate, aspirin, calcium supplements, amlodipine, nifedipine, methyldopa, enalapril, hydralazine and labetalol, using any valid laboratory methods. Data collection and analysis Two reviewers independently screened the studies, extracted data and assessed the quality. Results were reported narratively by type of medicine. Main results Of 5669 citations screened, 33 studies from 27 countries were included. Five quality studies on magnesium sulphate- two (Nigeria and USA) found substandard medicine due to failing API specification and contaminants, respectively. Another study from Nigeria and a multi-country study (10 lower-middle- and low-income countries) found poor-quality due to failing the pH criteria. Seven of eight studies evaluating aspirin found quality issues, including degraded medicines in five studies (Brazil, USA, Yugoslavia and Pakistan). Five studies of calcium supplements found quality issues, particularly heavy metal contamination. Of 15 antihypertensives quality studies, 12 found substandard medicines and one study identified counterfeit medicines. Conclusion We identified multiple findings of poor quality across all types of medicines used in hypertensive disorders of pregnancy, raising concerns regarding their safety and effectiveness.

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