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Al-Fozan H, Firwana B, Al Kadri H, Hassan S, Tulandi T. Preoperative ripening of the cervix before operative hysteroscopy. *Cochrane Database of Systematic Reviews* 2015, Issue 4. Art. No.: CD005998. DOI: 10.1002/14651858.CD005998.pub2.

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[Intervention Review]

Preoperative ripening of the cervix before operative hysteroscopy

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Editorial group: Cochrane Gynaecology and Fertility Group. **Publication status and date:** New, published in Issue 4, 2015.

Citation: Al-Fozan H, Firwana B, Al Kadri H, Hassan S, Tulandi T. Preoperative ripening of the cervix before operative hysteroscopy. *Cochrane Database of Systematic Reviews* 2015, Issue 4. Art. No.: CD005998. DOI: 10.1002/14651858.CD005998.pub2.

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ABSTRACT

Background

Hysteroscopy is an operation in which the gynaecologist examines the uterine cavity using a small telescopic instrument (hysteroscope) inserted via the vagina and the cervix. Almost 50% of hysteroscopic complications are related to difficulty with cervical entry. Potential complications include cervical tears, creation of a false passage, perforation, bleeding, or simply difficulty in entering the internal os (between the cervix and the uterus) with the hysteroscope. These complications may possibly be reduced with adequate preparation of the cervix (cervical ripening) prior to hysteroscopy. Cervical ripening agents include oral or vaginal prostaglandin, which can be synthetic (e.g misoprostol) or natural (e.g. dinoprostone) and vaginal osmotic dilators, which can be naturally occurring (e.g. laminaria) or synthetic.

Objectives

To determine whether preoperative cervical preparation facilitates cervical dilatation and reduces the complications of operative hysteroscopy in women undergoing the procedure for any condition.

Search methods

In August 2014 we searched sources including the Menstrual Disorders and Subfertility Group (MDSG) Trials Register, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, PsycINFO, CINAHL, ClinicalTrials.gov and reference lists of relevant articles. We searched for published and unpublished studies in any language.

Selection criteria

Two review authors independently selected randomised controlled trials (RCTs) of cervical ripening agents used before operative hysteroscopy in pre- and postmenopausal women. Cervical ripening agents could be compared to each other, placebo or no treatment.

Data collection and analysis

Data extraction and quality assessment were conducted independently by two review authors. The primary review outcomes were effectiveness of cervical dilatation (defined as the proportion of women requiring mechanical cervical dilatation) and intraoperative complications. Secondary outcomes were mean time required to dilate the cervix, preoperative pain, cervical width, abandonment of the procedure, side effects of dilating agents and duration of surgery. We calculated odds ratios (ORs) for dichotomous outcomes and mean differences (MDs) for continuous outcomes, with 95% confidence intervals (CIs). Data were statistically pooled where appropriate. Heterogeneity was assessed using the I² statistic. The overall quality of the evidence was assessed using GRADE methods.

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Main results

Nineteen RCTs with a total of 1870 participants were included. They compared misoprostol with no treatment or placebo, dinoprostone or osmotic dilators.

Misoprostol was more effective for cervical dilatation than placebo or no intervention, with fewer women requiring mechanical dilatation (OR 0.08, 95% CI 0.04 to 0.16, five RCTs, 441 participants, I²=0%, moderate quality evidence). This suggests that in a population in which 80% of women undergoing hysteroscopy require mechanical dilatation without use of preoperative ripening agents, use of misoprostol will reduce the need for mechanical dilatation to between 14% and 39%. Misoprostol was associated with fewer intraoperative complications (OR 0.37, 95% CI 0.18 to 0.77, 12 RCTs, 901 participants, I²=0%, moderate quality evidence). This suggests that in a population in which 3% of women undergoing hysteroscopy experience intraoperative complications without use of preoperative ripening agents, use of misoprostol will reduce the risk of complications to 2% or less.

When specific complications were considered, the misoprostol group had a lower rate of cervical laceration or tearing (OR 0.25, 95% CI 0.11 to 0.57, nine RCTS, 669 women, I²=0%, moderate quality evidence) or false track formation (OR 0.34, 95% CI 0.12 to 0.97, seven RCTs, 560 participants, I²=0%, moderate quality evidence). There was no evidence of a difference between the groups in rates of uterine perforation (0.42, 95% CI 0.13 to 1.38, seven RCTs, 455 participants, I²=0%, low quality evidence) or uterine bleeding (OR 0.51, 95% CI 0.10 to 2.49, four RCTs, 340 participants, I²=0%, low quality evidence). Some treatment side effects (mild abdominal pain, vaginal bleeding, and increased body temperature) were more common in the misoprostol group.

Compared with dinoprostone, misoprostol was associated with more effective cervical dilatation, with fewer women requiring mechanical dilatation (OR 0.58; 95% CI 0.34 to 0.98; one RCT, 310 participants, low quality evidence) and with fewer intraoperative complications (OR 0.32; 95% CI 0.12 to 0.83, one RCT, 310 participants, low quality evidence). However treatment side effects were more common in the misoprostol arm.

Compared to osmotic dilatation (laminaria), misoprostol was associated with less effective cervical dilatation, with more women in the misoprostol group requiring mechanical dilatation (OR 5.96, 95% CI 2.61 to 13.59, one RCT, 110 participants, low quality evidence). There was no evidence of a difference between misoprostol and osmotic dilators in intraoperative complication rates (OR 5.14, 95% CI 0.24 to 109.01, three RCTs, 354 participants, low quality evidence), with only two events reported altogether.

The overall quality of the evidence ranged from low to moderate. The main limitations in the evidence were imprecision and poor reporting of study methods.

Authors' conclusions

There is moderate quality evidence that use of misoprostol for preoperative ripening of the cervix before operative hysteroscopy is more effective than placebo or no treatment and is associated with fewer intraoperative complications such as lacerations and false tracks. However misoprostol is associated with more side effects, including preoperative pain and vaginal bleeding. There is low quality evidence to suggest that misoprostol has fewer intraoperative complications and is more effective than dinoprostone.

There is also low quality evidence to suggest that laminaria may be more effective than misoprostol, with uncertain effects for complication rates. However the possible benefits of laminaria need to be weighed against the inconvenience of its insertion and retention for one to two days.

PLAIN LANGUAGE SUMMARY

Preparing the cervix with different ripening agents before operative hysteroscopy

Review question

Are cervical ripening agents effective for dilating the cervix before operative hysteroscopy and do they reduce the risk of complications during the surgery?

Background

Hysteroscopy is an operation in which the gynaecologist examines the uterine cavity using a small telescope (hysteroscope) inserted via the vagina and the cervix. Potential complications of hysteroscopy include cervical tears, formation of a false passage and uterine perforation. Cervical ripening agents are used with the aim of making it easier for the hysteroscope to pass through the cervix and reducing the risk of complications. Ripening agents include different types of prostaglandins (for example misoprostol and dinoprostone) which are administered either orally or vaginally. Osmotic agents are also used, and are administered vaginally. One osmotic agent is laminaria, a seaweed based product. Cochrane reviewers assessed the evidence about different ripening agents. The evidence is current to August 2014.

Study characteristics

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We included 19 randomised controlled trials (1870 participants) of premenopausal and postmenopausal women undergoing hysteroscopic surgery for a variety of conditions. They compared misoprostol with placebo or no treatment, dinoprostone, and osmotic agents.

Key results

There is moderate quality evidence that misoprostol is safer and is more effective for cervical ripening than placebo or no treatment, and that is associated with fewer complications occurring during the operation, with lower rates of lacerations and false tracks. However misoprostol is associated with more side effects such as preoperative pain and vaginal bleeding.

There is low quality evidence that misoprostol may be safer and more effective than dinoprostone, and that it may be associated with fewer complications occurring during the operation. There is also low quality evidence that laminaria may be more effective than misoprostol. However, the possible benefits of laminaria need to be weighed against the inconvenience of its insertion and retention for one to two days.

Quality of the evidence

The quality of the evidence ranged from low to moderate. The main limitations in the evidence were imprecision and poor reporting of study methods. The evidence is current to August 2014.