Evidence tables for review question: What is the effectiveness of prophylactic antibiotics for preventing postnatal infections in assisted vaginal birth?

Liabsuetrakul, 2020

Bibliographic Reference	Liabsuetrakul, Tippawan; Choobun, Thanapan; Peeyananjarassri, Krantarat; Islam, Q. Monir; Antibiotic prophylaxis for operative vaginal delivery; Cochrane Database of Systematic Reviews; 2020; vol. 2020 (no. 3); cd004455

Study details

Country/ies where study was carried out	Heitmann 1989 United States Knight 2019 United Kingdom
Study type	Cochrane Systematic Review of Randomised Controlled Trials
Study dates	Heitmann 1989 September 1986 to February 1989 Knight 2019 13 March 2016 to 13 June 2018
Inclusion criteria	Heitmann 1989 not specified. *Knight 2019 • 16 years or older • able to give informed consent • had undergone operative vaginal birth at 36 weeks or more gestation

	• women who had antibiotics antenatally or intrapartum (such as for prolonged rupture of membranes) were not excluded.
Exclusion criteria	Heitmann 1989 • Chorioamnionitis or other infections • allergic to penicillin or cephalosporins. Knight 2019 • Any clinical indication for antibiotic administration after delivery (such as, confirmed antenatal or intrapartum infection, third or fourth degree perineal tears) • known allergy to penicillin or any of the components of amoxicillin and clavulanic acid • history of anaphylaxis to another beta-lactam agent.
Patient characteristics	*Heitmann 1989 **Maternal age - mean (SD)** Intervention: 21.38 (4.98), Comparator: 20.73 (4.48) **Parity - mean (SD)** Intervention: 0.46 (0.92), Comparator: 0.47 (0.79) **Actual mode of birth** Forceps: Intervention: 43.2%, Comparator: 41.3% Vacuum: Intervention: 56.8%, Comparator: 58.7% *No information on whether presentation was non-cephalic. No significant differences between groups.

	*Knight 2019 **Maternal age - mean (SD)** Intervention: 30.3 (5.37), Comparator: 30.2 (5.49) **Gestational age - median (IQR)** Intervention: 40 (39 to 41), Comparator: 40 (39 to 41) **(36 to <38:** Intervention: 136 (8%), Comparator: 123 (7%)) **BMI at booking - median (IQR)** Intervention: 25 (22 to 28), Comparator: 25 (22 to 29) **Twin pregnancy - number (%)** Intervention: 11 (1%), Comparator: 9 (1%) **Actual mode of birth - number (%)** Spontaneous vaginal: Intervention: 7 (<1%), Comparator: 3 (<1%) Forceps: Intervention: 1086 (63%), Comparator: 1148 (67%) Vacuum extraction: Intervention: 633 (37%), Comparator: 563 (33%) *Study specifies women were not excluded based on the station of the fetal head at the time of instrument application, nor specific mention of exclusion of non-cephalic presentation. Characteristics between groups similar.

Intervention(s)/control	Heitmann 1989 Intervention: 2g of cefotetan given IV after cord clamping Control: No treatment Knight 2019 Intervention: A single dose of IV amoxicillin (1g) and clavulanic acid (200mg), as soon as possible after giving birth, and no more than 6 hours. Control: Placebo. 20ml of IV sterile 0.9% saline within the same timeframe. *Antibiotics were given after birth in both studies *Route of administration was IV for both studies *Single dose for both studies *Type of antibiotic: Heitmann 1989: cephalosporin Knight 2019: co-amoxiclav *Both studies had instrumental and forceps delivery, but data not analysed separately. *No information on Group B Streptococcus test, although other infections or antibiotics for other infections excluded from populations.
Sources of funding	Heitmann 1989 Not specified Knight 2019 Not industry funded
Sample size	Heitmann 1989 N=393 women undergoing forceps or vacuum birth Intervention, n=192 Control, n=201 Knight 2019

	N=3420 women undergoing forceps or vacuum birth Intervention, n=1715 Control, n=1705

Outcomes

Heitmann 1989

Outcome	Prophylactic antibiotics, , N = 192	Control, , N = 201
Endometritis No of events	n = 0	n = 7

Knight 2019 (ANODE)

Outcome	Prophylactic antibiotics, , N = 1715	Control, , N = 1705
Endometritis No of events	n = 15	n = 23
Infected episiotomy/laceration Superficial or deep perineal wound; organ or space infection; No of events	n = 111	n = 222
Systemic sepsis (*) according to modified SIRS criteria for pregnancy No of events	n = 6	n = 10
Maternal adverse reactions No of events	n = 2	n = 1
Breastfeeding at 6 weeks No of events	n = 662	n = 657

Outcome	Prophylactic antibiotics, , N = 1715	Control, , N = 1705
Perineal pain at 6 weeks post-delivery No of events	n = 592	n = 707

Critical appraisal - NGA Critical appraisal - ROBIS checklist

Section	Question	Answer
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	Low
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	Low
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	Low *(Some study characteristics were not extracted relevant to the protocol, but low risk of bias as the main ones were for the Cochrane review)*
Synthesis and findings	Concerns regarding the synthesis and findings	Low *(Sensitivity analysis was not carried out as only 2 studies were included, however the authors addressed this.)*
Overall study ratings	Overall risk of bias	Low
Overall study ratings	Applicability as a source of data	Fully applicable

Limitations for each of the included studies assessed with the Cochrane Risk of Bias Tool v1, based on the Cochrane review assessments

Study	Answer
Heitmann 1989	Random sequence generation (selection bias): Low risk Allocation concealment (selection bias): Some concerns Blinding of participants and personnel (performance bias): Some concerns Blinding of outcome assessment (detection bias): Some concerns Incomplete outcome data (attrition bias): Low risk Selective reporting (reporting bias): Some concerns Other bias: Low risk
Knight 2019	Random sequence generation (selection bias): Low risk Allocation concealment (selection bias): Low risk Blinding of participants and personnel (performance bias): Low risk Blinding of outcome assessment (detection bias): Low risk Incomplete outcome data (attrition bias): Low risk Selective reporting (reporting bias): Low risk Other bias: Low risk

IQR: interquartile range; IV: intravenous; SD: standard deviation; SIRS: systemic inflammatory response syndrome