A comparison of vaginal prostaglandins and balloon catheters for cervical ripening prior to labor induction

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BACKGROUND:

Induction of labor is one of the most common obstetric interventions, and half of all inductions require cervical ripening. Trials comparing hormonal (vaginal prostaglandins) and mechanical (balloon catheter) methods are often underpowered for safety outcomes. We aim to overcome this issue and investigate these outcomes through use of individual patient data meta-analysis.

METHODS

Individual participant data was sought from eligible RCTs comparing vaginal prostaglandins and balloon catheters.

Data was available for analysis from 12 studies including 5460 participants.

Primary Outcomes:

- Efficacy
- Rate of Caesarean section
- Indication for Caesarean section
- Perinatal safety (composite)
- Apgar <7 at 5 mins
- Umbilical cord arterial pH <7.1
- Admission to NICU
- Seizures
- Maternal safety (composite)
- Admission to ICU
- Infection
- Severe PPH
- Death

Balloon cervical ripening is safer for neonates as compared to vaginal prostaglandins, with comparable rates of Caesarean sections

Rates of composite neonatal adverse outcomes for vaginal prostaglandins and balloon catheters

| Study | No. pts | |
|--|-------------------|--------|
| Jozwiak 2011 Henry 2013 | 824 101 | • |
| Beckmann 2020 | 448 | • |
| Diguisto 2021 Edwards 2014 | 1214 376 | |
| Jozwiak 2014 Jozwiak 2013 Prager 2008 | 120 231 569 | |
| Pennell 2009 Oliveira 2010 | 329 160 | |
| Moraes Filho 2002 | 80 | |
| Overall, REML+HKSJ | 4452 | - - |
| with estimated 95% pre (I ² = 0.0%, p = 0.913) | sulctive interva | |

.25

| | | | Odds ratio | % |
|---|-------------|---|---------------------|--------|
| | | | (95% CI) | Weight |
| | | | | |
| + | | | 0.70 (0.46, 1.06) | 18.05 |
| * | | - | 1.02 (0.37, 2.84) | 2.97 |
| + | | | 0.65 (0.42, 1.03) | 15.28 |
| • | | | 0.90 (0.63, 1.29) | 23.90 |
| • | | | 0.95 (0.55, 1.63) | 10.67 |
| - | • | | 1.40 (0.56, 3.45) | 3.79 |
| | | | 0.82 (0.41, 1.64) | 6.42 |
| | | | 0.82 (0.37, 1.82) | 4.83 |
| + | | | 0.69 (0.42, 1.14) | 12.42 |
| | | _ | 0.81 (0.21, 3.16) | 1.68 |
| | | | (Insufficient data) | |
| | | | (Insufficient data) | |
| > | | | 0.80 (0.70, 0.92) | 100.00 |
| | | | (0.70, 0.92) | |
| | | | | |
| | | | | |
| 1 | | 3 | | |
| | Favours PGE | | | |

RESULTS

Caesarean sections rates are comparable \bullet between both methods of cervical ripening sOR 1.09 (95% CI 0.95 - 1.24)

| | No. | | Odds ratio | % |
|------------------------------------|---------------|------------------|------------------|------------|
| Study | pts | | (95% CI) | Weight |
| Moraes Filho 2002 | 240 | | • 1.56 (0.90, 2. | 71) 5.34 |
| Jozwiak 2011 | 823 | | 1.15 (0.81, 1. | 62) 13.50 |
| Henry 2013 | 91 | | 1.31 (0.54, 3. | 15) 2.10 |
| Beckmann 2020 | 448 | -++ | • 1.33 (0.87, 2. | 04) 8.88 |
| Diguisto 2021 | 1214 | | 1.07 (0.81, 1. | 41) 21.14 |
| Edwards 2014 | 376 | | 0.72 (0.46, 1. | 12) 8.20 |
| Jozwiak 2014 | 120 | | | 89) 1.82 |
| Jozwiak 2013 | 231 | | 1.02 (0.51, 2. | 04) 3.36 |
| Prager 2008 | 569 | | 0.86 (0.56, 1. | 34) 8.44 |
| Pennell 2009 | 330 | | 1.10 (0.68, 1. | 76) 7.15 |
| Oliveira 2010 | 160 | | 1.56 (0.78, 3. | 13) 3.35 |
| Løkkegaard 2015 | 812 | - | 1.01 (0.74, 1. | 38) 16.71 |
| Overall, REML+HKSJ | 5414 | \mathbf{k} | > 1.09 (0.95, 1. | 24) 100.00 |
| with estimated 95% pre | dictive inter | rval | (0.95, 1 | 25) |
| (l ² = 0.0%, p = 0.553) | | | | |
| | .25 | 1 | 6 | |
| | .20 | Favours balloons | Favours PGE | |

- Fewer instrumental births for fetal distress with balloon catheter
- aOR 1.20 (95% CI 0.91 1.58)
- Uterine hyperstimulation was reduced with use of balloon catheter
- sHR 0.35 (0.19 0.64)

OTE: Weights are from random-effects mode

- Balloon catheter significantly reduced chance of arterial cord pH <7.10
- aOR 0.72 (95% CI 0.53 0.98)
- No significant difference was identified for composite adverse maternal outcomes
- aOR 1.02 (95% CI 0.89 1.18)

CONCLUSION

- Vaginal prostaglandins result in a similar rate of Caesarean sections when compared to balloon catheters
- However they are associated with significantly higher chances of adverse neonatal outcomes, including arterial cord pH <7.1
- Balloon catheters reduced the chance of hyperstimulation or instrumental birth for foetal distress

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