Implementation of Evidence Based Medicine in Clinical Teaching and Practices

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Conflict of Interest

• None

What is evidence based?

- The process of systemically:
 - finding,
 - appraising, and
 - using

research findings as the basis for clinical decisions.

[National Institute for Health and Care Excellence (NICE), 2004]

What is Evidence-based clinical practice?

- Evidence-based clinical practice therefore involves integrating:
 - individual clinical practice and
 - the best available evidence from research with
 - patient preferences

[National Institute for Health and Care Excellence (NICE), 2004]

BMC Medical Research Methodology



Study protocol

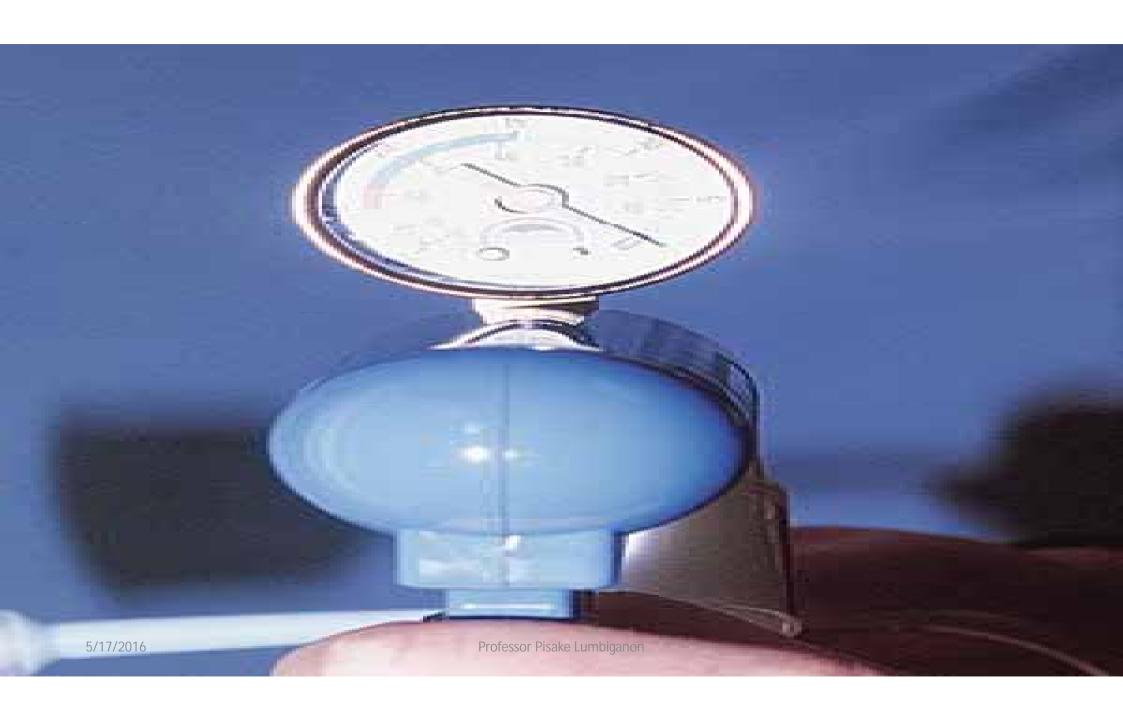
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Optimising reproductive and child health outcomes by building evidence-based research and practice in South East Asia (SEA-ORCHID): study protocol

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Clinical question

PICO

P = Population

I = Intervention

C = Comparison

O = Outcomes

Clinical question

Is rapid negative pressure application as effective and safe as stepwise method?

Quality of Evidence

- la. Research synthesis of RCT
- Ib. At least one properly designed RCT
- IIa. At least one well designed controlled trial without randomization
- Ilb. At least one well-designed cohort study
- III. Evidence obtained from case control or descriptive studies
- IV. Opinion of respected authorities.

[National Institute for Health and Care Excellence (NICE), 2004]

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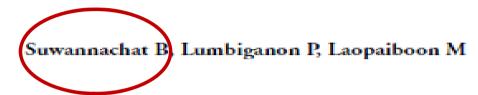
Peter Coxeter, Chris B Del Mar, Leanne McGregor, Elaine M Beller, Tammy C Hoffmann 12 November 2015

Interventions for treating proximal humeral fractures in adults

Helen HG Handoll, Stig Brorson 11 November 2015



Rapid versus stepwise negative pressure application for vacuum extraction assisted vaginal delivery (Review)





Professor Pisake Lumbiganon

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials and quasi-randomized controlled trials.

Types of participants

Women undergoing vacuum extraction assisted vaginal delivery.

Types of interventions

Rapid (within two minutes) versus stepwise (as defined by trialists) negative pressure application for vacuum extraction assisted vaginal delivery.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (4 April 2012).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

- monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
 - 2. weekly searches of MEDLINE;
 - weekly searches of EMBASE;
- handsearches of 30 journals and the proceedings of major conferences;
- weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Assessment of Risk of Bias

- 1. Random sequence generation
- 2. Allocation concealment (Selection bias)
- 3. Blinding
 - a) Participants and Personnel (Performance bias)
 - b) Outcome assessment (Detection bias)
- 4. Incomplete outcome data
- 5. Selective reporting
- 6. Other biases

Systematic review

- Included one trial involving 94 women.
- Duration of vacuum procedure was reduced in rapid application group - 6.10 minutes (95% confidence interval -8.83 to -3.37)
- There were no significant differences in
 - Maternal and fetal morbidity
- Not enough evidence to recommend

(Suwannachat B 2008)

ABSTRACT

Background

Vacuum extraction is a common technique of assisted vaginal delivery. Traditionally, it has been recommended that the pressure is increased slowly in a stepwise procedure; some have advocated rapid increases in pressure.

Objectives

To assess the efficacy and safety of rapid versus stepwise negative pressure application for assisted vaginal delivery by vacuum extraction.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (March 2008).

Selection criteria

Randomized controlled trials and quasi-randomized controlled trials of rapid compared with stepwise increase in negative pressure application of vacuum extraction.

Data collection and analysis

Two authors independently assessed trial quality and extracted data.

Main results

One trial of 94 women was included. Duration of vacuum procedure was reduced in rapid application group (mean difference - 6.10 minutes, 95% confidence interval -8.83 to -3.37). There were no significant differences in detachment rate, degree of perineal tears, Apgar score less than seven at one and five minutes, umbilical venous pH less than 7.2, scalp laceration greater than a quarter, cephalhematoma and number of tractions.

Rapid versus stepwise negative pressure application for vacuum extraction assisted vaginal delivery (Review) Copyright © 2008 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Authors' conclusions

The rapid negative pressure application for vacuum assisted vaginal birth reduces the duration of the procedure whilst there is no evidence of differences in maternal and neonatal outcome. Due to a small number of participants in the single included trial, the evidence is limited and either policy may be employed until further controlled trials provide conclusive evidence of benefit from one or other method.

PLAIN LANGUAGE SUMMARY

Applying negative pressure rapidly or in steps for vacuum extraction assisted vaginal delivery

Assisted vaginal delivery is an important part of obstetric care. Indications for its use include prolonged second stage of labour, actual or potential fetal compromise or distress and to shorten labour. The established method is to grasp the fetal head with obstetric forceps and turn and position the head to facilitate the descent and birth of the infant. A vacuum extractor is becoming the method of choice as it is less likely to injure the mother although failure of attempted vacuum extraction may occur more often than with forceps. The vacuum extractor is contraindicated with face, brow or breech presentation and if the gestational age of the fetus is less than 34 weeks because of the risk of damage to the scalp (cephalhematoma) and intracranial bleeding.

What should we do next?

Randomized controlled trial

• Sample size : 660

• Multi-centre

Note: This record shows only the 20 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, primary register.

Register: ANZCTR

Last refreshed on: 10 February 2009

Main ID: ACTRN12608000443392

Date of registration: 05/09/2008

Primary sponsor: Kalasin Hospital

Public title: Rapid versus stepwise negative pressure application for vacuum extr

application for vacuum extraction assisted vaginal delivery

Scientific title: Rapid versus stepwise negative pressure application for vacuum extr

Date of first enrolment: 1/10/2008

Target sample size: 330

Recruitment status: Not yet recruiting

URL: http://www.anzctr.org.au/ACTRN12608000443392.aspx

Study type: Interventional

Study design: Randomised controlled trial Parallel

Countries of recruitment

Thailand

Contacts

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Affiliation: Affiliation:

Key inclusion & exclusion criteria

Inclusion criteria: Uncomplicated singleton pregnancy, more than 34 weeks of gestation, cephalic presentation.

Exclusion criteria: • Refusal to give informed consent • the woman is not entitled to give informed consent e.g. minors without

Name:

Email:

Address:

Telephone:

Rapid versus stepwise application of negative pressure in vacuum extraction-assisted vaginal delivery: a multicentre randomised controlled non-inferiority trial

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Accepted 14 March 2011. Published Online 18 May 2011.

Objective To evaluate whether the application of rapid negative pressure for vacuum-assisted delivery is as effective and safe as the

of vacuum extraction, and maternal and neonatal complications.

Clinical

Rapid increase in negative pressure safe in vacuum-assisted delivery

Last Updated: 2011-06-15 16:00:02 -0400 (Reuters Health)

By David Douglas

NEW YORK (Reuters Health) - A gradual stepwise increase in negative pressure during vacuum extraction - the usual approach - doesn't appear to offer any advantages over a faster method, Thai researchers report.

"Rapid application vacuum extraction" cut about five minutes from the typical procedure in a recent study. In some cases, "this is a critical period," said coauthor Dr. Pisake Lumbiganon in email to Reuters Health.

In a report online May 18th in BJOG, Dr. Lumbiganon of Khon Kaen University and colleagues note that the rationale behind the stepwise method, which takes 8 to 10 minutes, was that a gradual increase in negative pressure would allow the vacuum to become more firmly attached to the fetal head.

More recent research has suggested that traction force is comparable after one to two minutes, however.

Rapid versus stepwise negative pressure application for vacuum extraction assisted vaginal delivery (Review)

Suwannachat B, Lumbiganon P, Laopaiboon M



This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2012, Issue 8

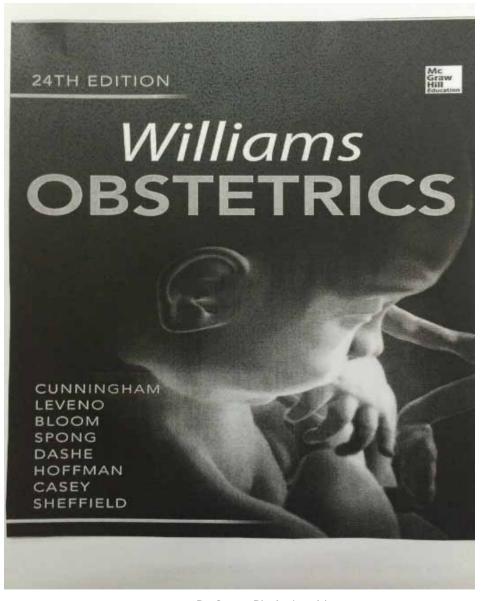
Authors' conclusions

The rapid negative pressure application for vacuum assisted vaginal birth reduces duration of the procedure whilst there is no evidence of differences in maternal and neonatal outcomes. Rapid method of negative application should be recommended for vacuum extraction assisted vaginal delivery.

PLAIN LANGUAGE SUMMARY

Applying negative pressure rapidly or in steps for vacuum extraction assisted vaginal delivery

Assisted vaginal delivery is an important part of obstetric care. Indications for its use include prolonged second stage of labour, actual or potential fetal compromise or distress, and to shorten labour. The established methods facilitate the descent and birth of the infant. A vacuum extractor is becoming the method of choice as it is less likely to injure the mother although failure of attempted vacuum extraction may occur more often than with forceps. Rapid application addresses the benefit of vacuum extraction that can be used when rapid delivery is required. Two good quality randomized controlled trials involving 754 women were identified. Rapid negative pressure application reduced the duration of the procedure without any evidence of differences in outcomes for the mother or infant. Rapid method of negative pressure application should be recommended for vacuum extraction assisted vaginal delivery.



During cup placement, maternal soft tissue entrapment predisposes the mother to lacerations and virtually ensures cup dislodgement. Thus, the entire cup circumference should be palpated both before and after the vacuum has been created as well as prior to traction to exclude such entrapment. Gradual vacuum creation is advocated by some and is generated by increasing the suction in increments of 0.2 kg/cm² every 2 minutes until a total negative pressure of 0.8 kg/cm² is reached (Table 29-3). That said, other studies have shown that negative pressure can be increased to 0.8 kg/cm² in < 2 minutes without a significant difference in efficacy or in maternal and fetal outcomes (Suwannachat, 2011, 2012).

Subject: Designation of Clinical Epidemiology Unit, Faculty of Medicine, Khon Kaen University as a WHO Collaborating Centre for Research Synthesis in Reproductive Health (WHOCC No. THA-63)

I have pleasure in informing you that the World Health Organization, after consultation with your Government, has designated Clinical Epidemiology Unit, Faculty of Medicine, Khon Kaen University as a WHO Collaborating Centre for Research Synthesis in Reproductive Health. As previously agreed, Mr Pisake Lumbiganon, Clinical Epidemiology Unit, Faculty of Medicine will be the Head of the Centre. The terms of reference of the Centre are attached. Should there be any changes in the future that might affect this arrangement, I should be grateful if you would inform me without delay.

Take home message

- Life-long learning
- Routine to Research
- Clinical question (PICO)
- Literature search
 - Systematic (Cochrane review)
 - Comprehensive search
 - Risk of bias assessment
 - Data synthesis and interpretation
- Evidence generation
 - Appropriate study design
 - Collaboration (multicentre study)
- Update evidence
- Implementation
- Role model of faculty members