CLINICAL OBSTETRICS

Abstracts 53 – 61

Moderators: Sean Blackwell, MD; Aaron Caughey, MD

53 Comparison of three regimens using mifepristone and misoprostol for second trimester pregnancy termination

Jan Dickinson[1], Belinda Jennings[2], Dorota Doherty[1]
[1]The University of Western Australia, School of Women's and Infants' Health, Perth, WA, Australia, [2]King Edward Memorial Hospital, Obstetrics and Gynaecology, Perth, WA, Australia

OBJECTIVE: To compare the efficacy of 3 regimens for the administration of misoprostol after mifepristone priming in second trimester pregnancy termination.

STUDY DESIGN: Prospective randomized trial of pregnancy termination with misoprostol following mifepristone priming at 14-24 weeks gestation. Women received 200mg of mifepristone orally followed 24-48 hours later by 800 mcg misoprostol vaginally. Three regimens for the subsequent misoprostol dosing were compared: 400 mcg oral misoprostol 3-hourly (Group 1), 400 mcg vaginal misoprostol 4-hourly (Group 2), and 400 mcg sublingual misoprostol 3-hourly (Group 3). The primary study outcome was the percentage of women undelivered 12 hours after the administration of the misoprostol loading dose in the 3 groups.

RESULTS: 302 women were randomized: 100 to Group 1, 100 to Group 2 and 102 to Group 3. There was no difference in maternal age, race, parity or prior uterine surgery between groups. The median gestation at recruitment was: Group 1 19.1 weeks (interquartile range [IQR] 17.2-20.8), Group 2 19.4 weeks (IQR 17.3-20.4), Group 3 19.7 weeks (IQR 17.6-21.0); p=0.577. The duration from mifepristone administration until misoprostol commencement did not differ: Group 1 37.4 hours (IQR 27.8-42.8), Group 2 31.9 hours (IQR 26.8-41.7), Group 3 29.7 (IQR 26.1-41.6); p=0.177. Duration of termination differed significantly: Group 1 9.5 hours (IQR 6.6-15.4), Group 2 7.8 hours (IQR 5.8-11.5) and Group 3 7.0 hours (IQR 5.8-11.1); p=0.005, with 38% (n=38) of women in Group 1, 23% (n=23) in Group 2 and 22.5% (n=23) in Group 3 undelivered at 12 hours, and 13% (n=13) of women in Group 1, 4% (n=4) in Group 2 and 5.9% (n=6) in Group 3 undelivered at 24 hours. There was no difference in the occurrence of complications between the groups.

CONCLUSION: Vaginal or sublingual misoprostol administered after a vaginal loading dose in second trimester pregnancy termination with mifepristone priming significantly decreases the procedural duration compared with an oral misoprostol regimen.

54 Remifentanil patient controlled analgesia versus epidural analgesia in labor; a randomized controlled equivalence trial

Liv Freeman[1], Kitty Bloemenkamp[1], Maureen Franssen[2], Dimitri Papatsonis[3], Markus Hollmann[4], Mallory Woiski[5], Martina Porath[6], Hans van den Berg[7], Erik van Beek[8], Nico Schuitemaker[9], Marko Sikkema[10], Sabine Logtenberg[11], Martijn Oudijk[12], Caroline Bax[13], Paulien van der Salm[14], Elske van den Akker-van Marle[15], Saskia le Cessie[16], Jan van Lith[1], Michel Struys[17], Albert Dahan[18], Ben Willem Mol[19], Johanna Middeldorp[1]
[1]Leiden University Medical Center, Obstetrics, Leiden, Netherlands, [2]University Medical Center Groningen, Obstetrics and Gynecology, Groningen, Netherlands, [3]Amphia Hospital, Obstetrics and Gynecology, Breda, Netherlands, [4]Academic Medical Center, Anesthesiology, Amsterdam, Netherlands, [5]St. Radboud University Medical Center, Obstetrics and Gynecology, Nijmegen, Netherlands, [6]Maxima Medical Center, Obstetrics and Gynecology, Veldhoven, Netherlands, [7]Maxima Medical Centre, Anesthesiology, Veldhoven, Netherlands, [8]St. Antonius Hospital, Obstetrics and Gynecology, Nieuwegein, Netherlands, [9]Diakonessen Hospital, Obstetrics and Gynecology, Utrecht, Netherlands, [10]Hospital Group Twente, Obstetrics and Gynecology, Almelo, Netherlands, [11]Onze Lieve Vrouwe Gasthuis, Obstetrics and Gynecology, Amsterdam, Netherlands, [12]University Medical Center Utrecht, Obstetrics and Gynecology, Utrecht, Netherlands, [13]VU Medical Center, Obstetrics and Gynecology, Amsterdam, Netherlands, [14]Meander Medical Center, Obstetrics and Gynecology, Amersfoort, Netherlands, [15]Leiden Univerity Medical Center, Department of Medical Decision making, Leiden, Netherlands, [16]Leiden University Medical Center, Department of Medical Statistics, Leiden, Netherlands, [17]UMCG, Anesthesiology, Groningen, Netherlands, [18]LUMC, Anesthesiology, Leiden, Netherlands, [19]Academic Medical Center, Obstetrics and Gynecology, Amsterdam, Netherlands

OBJECTIVE: Recent studies suggest that remifentanil patient controlled analgesia (RPCA) is equivalent to epidural analgesia (EA) with respect to pain appreciation (satisfaction with pain relief). These studies were underpowered to detect a difference in pain appreciation. The aim of our study was to compare the effectiveness of RPCA with EA regarding pain appreciation.

STUDY DESIGN: We performed a multicenter equivalence RCT in 15 hospitals in the Netherlands (NTR 2551). We included healthy pregnant women who intended to deliver vaginally. After informed consent, they were randomized prior to the onset of active labor. Primary outcome was pain appreciation, measured hourly on a visual analogue scale (VAS), and expressed as area under the curve (AUC). The AUC gives a time-weighted measure of total pain appreciation. The AUC was calculated for the duration of labor and for the time that pain relief was administered. A higher AUC for pain appreciation represents higher satisfaction with pain (relief). Secondary outcomes were pain scores and maternal and neonatal variables.

To exclude a clinically significant difference in pain appreciation, defined as a difference of more than 10%, we needed 1136 women. Analysis was done by intention to treat.

RESULTS: 709 women were allocated to RPCA and 705 to EA. Baseline characteristics were comparable. 447 (65%) women in the

RPCA and 343 (51%) in the EA group received pain relief during labor (RR 1.3 95% CI 1.2-1.5). Among women allocated to RPCA 344 received nothing but RPCA, in the EA group 295 received just EA. 13% of the women switched to EA after RPCA. Maternal and neonatal outcomes were comparable. No serious adverse events occurred. The AUC for total pain appreciation during labor was 26.5 in the RPCA group versus 36.0 in the EA group (mean difference 9.5 (95% CI 5.0-13.0)).

CONCLUSION: RPCA is not equivalent to EA with respect to AUC for pain and pain appreciation scores and overall satisfaction in women with a request for pain relief during labor.

Primary outcome

	Remifentanil PCA N=687	Epidural analgesia N=671	Difference (95% CI)
AUC pain appreciation score During active labor (mean; IQR) N=613	26.5 (7.5-36.7)	36.0 (10.5-53.1)	9.5 (5.0-14.0)
AUC pain appreciation score After start pain relief (mean; IQR) N=447	24.9 (7.8-34.2)	40.6 (19.6-57.6)	15.7 (10.8-20.6)
AUC pain score During active labor (mean; IQR) N=720	28.5 (10.5-40.2)	23.8 (9.7-33.3)	4.7 (1.6-7.8)
AUC pain score After start pain relief (mean; IQR) N=497	26.6 (10.4-37.1)	19.8 (6.8-26.2)	6.8 (3.2-10.4)
Overall satisfaction score (mean; IQR) N=736	6.86 (6-8)	7.15 (7-8)	0.63 (0.23-1.03)

Area under the curve of pain appreciation scores, pain scores and overall appreciation score. Intention to treat analysis; analysis of scores during active labor and separate analysis of scores during administration of pain relief.

55 The relationship between cesarean delivery skin incision type and wound Complications in women with morbid obesity

Caroline Marrs[1], Hind Moussa[1], Bahaeddine Sibai[1], Sean Blackwell[1]

[1]UT Health- University of Texas Medical School at Houston, Department of Obstetrics, Gynecology and Reproductive Sciences, Houston, TX

OBJECTIVE: Currently, data are lacking from randomized clinical trials (RCTs) regarding the optimal cesarean delivery (CD) skin incision for women with obesity. Our purpose was to evaluate the association between types of skin incision (transverse vs. vertical) and the risk of wound complications in women with morbid obesity.

STUDY DESIGN: We performed a multicenter cohort study of morbidly obese (BMI $\geq$ 40 kg/m2) women with GA $\geq$ 24 weeks who had primary CD. Clinical characteristics and outcomes were compared between women who had a transverse or vertical skin incision. Outcomes studied were wound complication (infection, seroma, hematoma, evisceration, or dehiscence) and a composite of maternal complications (transfusion, hysterectomy, organ injury, coagulopathy, thromboembolic event, pulmonary edema, death). Multivariable logistic regression analyses were performed.

RESULTS: 3,200 women met study criteria (N=2,603 transverse [81.3%], N=597 vertical [18.7%]). In univariate comparisons, factors associated with vertical incision were white race, higher BMI, government insurance, diabetes, chorioamnionitis, non-lower segment hysterotomy, and emergency CD. Without adjusting for other factors, women with vertical incision were more likely to have wound complications (4.2% vs. 1.7%; p<0.001) and composite maternal complications (5.0% vs. 2.9%; p=0.02). Logistic regression analyses indicated that vertical skin incision was associated with a lower risk for wound complications (adjusted OR 0.32, 95% CI 0.17-0.62; p<0.001) but not composite maternal complications (adjusted OR 0.72, 95% CI 0.41-1.25; p=0.24).

CONCLUSION: In morbidly obese women undergoing primary CD, there is significant selection bias regarding whether a woman receives a transverse or vertical skin incision. Logistic regression analyses revealed that vertical skin incision was associated with a lower wound complication rate. Our observational data underscore the need for a RCT comparing skin incision types in this patient population.

56 Does a MFM centered L&D provider model put the "M" back in MFM?

Justin Brandt[1], Sindhu Srinivas[1], Michal Elovitz[1], Jamie Bastek[1]

[1]University of Pennsylvania Perelman School of Medicine, Maternal and Child Health Research Program, Obstetrics and Gynecology, Philadelphia, PA

OBJECTIVE: Maternal morbidity is rising in the US. Our objectives were to examine whether a labor & delivery (L&D) provider model with regular MFM presence 1) decreases the rates of maternal morbidity during delivery hospitalizations, 2) impacts OBGYN residents' perceptions of safety and educational opportunities, and 3) impacts OBGYN residents' CREOG performance.

STUDY DESIGN: We performed a retrospective cohort study to compare rates of maternal morbidity before and after the implementation of a MFM centered provider model on L&D. In the pre-exposure period (PRE: 7/1/2011-2/1/2012), MFM was available for high risk consultations, but did not regularly staff L&D; in the post-exposure period (POST: 7/1/2012-2/1/2013), MFM staffed all L&D patients daily from 7am-6pm. Morbidity was identified using ICD-9 codes based on previously published work. The primary outcome was a composite of maternal morbidities (Table). In addition, OBGYN residents exposed to both provider models completed an anonymous survey to compare both models, and their CREOG exam scores were compared.

RESULTS: Data from 4,715 deliveries (PRE: 2,286; POST: 2,429) were included. There were no differences in the composite of maternal morbidity or individual adverse maternal outcomes (Table). 81.3% of residents preferred the new provider model, with median 5-point Likert scores indicating perceived increases in safety (4.0), resident knowledge (4.0), and resident procedural comfort (4.0). Mean CREOG scores from PRE to POST improved in the 18 residents exposed to both models overall (+6.9%, p=0.015) and in the OB section (+6.1%, p=0.047).

CONCLUSION: Although the MFM centered provider model appears to have positively impacted resident perceptions of safety and education, it was not associated with significant changes in maternal morbidity. It is possible that a significant difference was not observed due to the infrequent occurrence of these outcomes. Moreover, a composite outcome based on ICD-9 codes may not adequately reflect the positive impact of this culture change on L&D.