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STUDY LEVELS OF EVIDENCE (LOE)

From the Centre for Evidence-Based Medicine, Oxford. For the most up-to-date levels of evidence, see www.cebm.net/levels_of_evidence.asp)

Therapy/Prevention/Etiology/Harm:

- 1a: Systematic reviews of randomized controlled trials
- 1b: Individual randomized controlled trials
- 1c: All or none randomized controlled trials
- 2a: Systematic reviews of cohort studies
- 2b: Individual cohort study or low-quality randomized controlled
- 2c: "Outcomes" research, ecological studies

Diagnosis:

- 1a: Systematic review of level-1 diagnostic studies
- 1b: Independent blind comparison of an appropriate spectrum of consecutive patients, all of whom have undergone both the diagnostic test and the reference standard, or a clinical decision rule not validated on a second set of patients
- 1c: Absolute SpPins and SnNouts
- 2a: Systematic review of level >2
- 2b: Independent blind or objective comparison, study confined to a narrow spectrum of study individuals, or a diagnostic clinical rule not validated in a test set

Prognosis:

- 1a: Systematic review of inception cohort studies
- 1b: Individual inception cohort study with >80% follow-up, or a clinical rule not validated on a second set of patients
- 1c: All or none case series
- 2a: Systematic review of either retrospective cohort studies or untreated control groups in RCTs
- 2b: Retrospective cohort study or follow-up of untreated control patients in an RCT, or clinical rule not validated in a test set
- 2c: "Outcomes" research

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Omega-3 Fatty Acids Not Effective for Depression in Patients With Coronary Heart Disease

Clinical Question

Does supplementation with omega-3 fatty acids improve the response to sertraline in patients with major depression and coronary heart disease (CHD)?

Bottom Line

In this study the addition of omega-3 fatty acids to sertraline in patients with major depression and CHD did not result in superior depression outcomes at 10 weeks compared with sertraline alone. (LOE = 1b)

Study Design

Randomized controlled trial (double-blinded)

Funding

Industry + govt

Allocation

Concealed

Setting

Outpatient (specialty)

Synopsis

These investigators identified 122 adults (mean age = 58 years) with a history of CHD meeting *Diagnostic and Statistical Manual, Fourth Edition* criteria for a current major depressive episode. Eligible patients randomly received (concealed allocation assignment) sertraline, 50 mg daily, plus either 2 g omega-3 fatty acid daily or corn oil placebo for 10 weeks. Individuals masked to treatment group assignment evaluated study participants at baseline and at 4 weeks and 10 weeks using standard validated scoring tools for depression and anxiety. Complete follow-up occurred for 94% of participants at 10 weeks. Using intention-to-treat analysis, no significant differences in improvement rates occurred between the 2 intervention groups. Adverse event rates were also similar in both groups. The study was 90% powered to detect a predetermined clinically significant treatment difference (difference of 4 points or more on the scoring tools).

REFERENCE

Carney RM, Freedland KE, Rubin EH, Rich MW, Steinmeyer BC, Harris WS. Omega-3 augmentation of sertraline in treatment of depression in patients with coronary heart disease. A randomized controlled trial. *JAMA*. 2009;302(15):1651-1657.

Induction of Labor May Be Beneficial at 36 Weeks With Hypertension

Clinical Question

Does induction of labor reduce maternal morbidity among pregnant women with gestational hypertension or mild preeclampsia at 36 to 41 weeks of gestation?

Bottom Line

There was no increased risk of harm due to induction of labor at 36 to 41 weeks' gestational age because of mild gestational hypertension or mild preeclampsia. The principal benefit was the reduction of the risk of progression to severe hypertension or severe preeclampsia among women at 38 weeks' gestation or more. (LOE = 1b-)

Study Design
Randomized controlled trial (nonblinded)

Funding
Government

Allocation
Concealed

Setting
Inpatient (any location)

Synopsis
In this Dutch open-label trial, 756 women with singleton pregnancies at 36 to 41 weeks' gestation in cephalic position and gestational hypertension or mild preeclampsia were randomized (allocation concealed) to receive induction of labor or usual care. Gestational hypertension was defined as diastolic blood pressure of 95 mm Hg or greater on 2 occasions at least 6 hours apart. Mild preeclampsia was defined as diastolic blood pressure of 90 mm Hg or greater on 2 occasions at least 6 hours apart plus proteinuria. Patients with severe hypertension or preeclampsia at the time of enrollment were excluded, defined as systolic blood pressure of 170 mm Hg or higher, diastolic blood pressure of 110 mm Hg or higher, or proteinuria of 5 g or more per 24 hours. Multiple other exclusions applied for maternal or fetal conditions. The sample of women randomized to the induction group were a somewhat higher-risk group because of slightly higher mean body mass indexes, more smokers, and lower education levels. Women allocated to the induction group underwent induction within 24 hours of randomization. Women allocated to the control group were monitored until spontaneous onset of labor, unless maternal or fetal condition indicated otherwise. Almost half the women in the expectant monitoring group underwent induction of labor, of which 72% had a medical indication and the remainder of inductions were by patient preference. The primary outcome was a composite measure of maternal mortality, maternal morbidity (including eclampsia, HELLP syndrome, pulmonary edema, thromboembolic disease, and placental abruption), progression to severe hypertension or proteinuria, and postpartum hemorrhage greater than 1000 mL blood loss. The primary outcome occurred in 31% of the induction group and 44% of the expectant group (number needed to treat [NNT] = 8; 95% CI, 5-17). Most of the difference was accounted for by progression to severe hypertension. The subgroup of women at 36 to 37 weeks' gestation did not benefit. There were no cases of maternal death, eclampsia, or placental abruption in either group. There was no difference in hospital length of stay. A 5% difference in spontaneous vaginal deliveries favoring the induction group (72% vs 67%) was not statistically significant.

REFERENCE

Koopmans CM, Bijlenga D, Groen H, et al, for the HYPITAT study group. Induction of labour versus expectant monitoring for gestational hypertension or mild pre-eclampsia after 36 weeks? gestation (HYPITAT): a multicentre, open-label randomized controlled trial. *Lancet.* 2009;374(9694):979-988.

In Utero SSRI Associated With Adverse Perinatal Events

Clinical Question
Is in utero selective serotonin reuptake inhibitor (SSRI) exposure associated with adverse perinatal events?

Bottom Line
In this well-done cohort study, the infants of women who took SSRIs during pregnancy had higher rates of preterm deliveries, higher rates of admission to the neonatal intensive care unit (NICU), and higher rates of Apgar scores less than 8. (LOE = 1b)

Study Design
Cohort (prospective)

Funding
Government

Setting
Outpatient (specialty)

Synopsis
Since 1989, these Danish investigators have administered a standard survey to all pregnant women who attend their prenatal center. At the time of birth, the midwife completes a standard coding sheet detailing the delivery, pregnancy complications, and so forth. The investigators report that more than 90% of women in their center have participated in this ongoing cohort study. This cohort was restricted to healthy women with singleton pregnancies that resulted in live births of infants with no malformations. For this article, the researchers classified 57 001 women into 3 potential groups: those who used SSRIs during pregnancy (n = 329), those who had received a diagnosis of depression or had received treatment for psychiatric illness but were not taking SSRIs during the actual pregnancy (n = 4902), and women who reported never having had a psychiatric illness (n = 51 770). The main outcome was gestational age at delivery, but the researchers also assessed birth weight, head circumference, Apgar scores, and admission to the NICU. They tried to take into account the effect of other factors that might influence these outcomes: parity, maternal age, prepregnancy body mass index, smoking, coffee and alcohol intake, marital status, previous pregnancy with a preterm and/or low-birth-weight infant, and education. Among women who used SSRIs while pregnant, 8.8% had preterm deliveries compared with 5% in each of the other groups; 16.4% of their infants were admitted to the NICU compared with 9% and 7.4% in the other groups, respec-

tively. Additionally, 4.9% of their infants had 5-minute Apgar scores less than 8 compared with 1% of the other group. The increased risk of these adverse events persisted after adjusting for the confounding factors. Approximately 3% of the women in each of the 3 groups gave birth to infants weighing less than 2500 g. The main limitation to this study is the reliance on patient self-report of their diagnoses and medication use.

REFERENCE

Lund N, Pedersen LH, Henriksen TB. Selective serotonin reuptake inhibitor exposure in utero and pregnancy outcomes. *Arch Pediatr Adolesc Med.* 2009;163(10):949-954.

Clinical Factors Identify Children at Low Risk of Traumatic Brain Injury

Clinical Question

Can clinical factors identify children with head injury who are at low risk for clinically important traumatic brain injury?

Bottom Line

In this large study, clinical factors identified which children with head injuries were unlikely to have a serious brain injury. Since computed tomography (CT) uses enormous amounts of radiation and children are especially vulnerable to potential adverse effects of radiation exposure, these factors can help reduce the use of CTs. (LOE = 1b-)

Study Design

Cohort (prospective)

Funding

Government

Setting

Emergency department

Synopsis

This team of researchers systematically evaluated more than 42 000 children presenting to emergency departments within 24 hours of sustaining head trauma. The researchers excluded children with trivial injuries (eg, trip and fall, walking into stationary objects) and children with penetrating injuries or preexisting neurologic disorders. Each child underwent a standardized clinical assessment. The researchers defined *clinically important brain injuries* as those that resulted in death, neurosurgical intervention, intubation, or more than 2 days in the hospital. A pediatric radiologist unaware of the child's clinical characteristics interpreted radiographs whenever CT was performed. The decision to perform CT was left to the discretion of the emergency department physician.

To identify children with clinically important brain injuries missed during the initial assessment, a researcher contacted the children's parents between 7 and 90 days of discharge from the emergency department. The researchers also split children into 2 age groups: younger than 2 years and 2 years and older. The researchers used data from the first 2 years of the study to derive clinical prediction rules. These were subsequently validated on children during the last 6 months of the study. Approximately one-third of the children had CT, of whom 5% had radiographic signs of traumatic brain injury, and 1% had clinically important brain injuries. For children younger than 2 years, the presence of any of the following clinical factors were useful in identifying children with clinically important brain injuries: altered mental status, occipital/parietal/temporal scalp hematoma, loss of consciousness for longer than 5 seconds, severe mechanism of injury, palpable skull fracture, or parent report of not acting normally.

The researchers defined *severe mechanism of injury* as motor vehicle crash with ejection of the child, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by a motorized vehicle; falls of more than 1.5 m (5 ft) for children 2 years and older and more than 0.9 m (3 ft) for those younger than 2 years; or head struck by a high-impact object. In the validation set, the presence of any of these factors was 100% sensitive (95% CI, 86.3%-100%) but only 54% specific (51.6%-55.8%). In other words, a child having none of these factors is very unlikely to have a serious injury and does not need CT. For children 2 years and older, the presence of any of the following clinical factors helps identify children with clinically important brain injuries: altered mental status, loss of consciousness, vomiting, severe mechanism of injury, clinical signs of basilar skull fracture, or severe headache. In the validation set, the presence of any of these factors was 97% sensitive (89%-99.6%), but only 60% specific (58.6%-61%). A child having none of these factors is very unlikely to have a serious injury and does not need CT.

REFERENCE

Kuppermann N, Holmes JF, Dayan PS, et al, for the Pediatric Emergency Care Applied Research Network (PECARN). Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study. *Lancet.* 2009;374(9696):1160-1170.

Cerclage Prevents Repeat PTB if Cervix Is Less Than 15 mm

Clinical Question

Does cerclage reduce preterm births before 35 weeks' gestation among women with previous preterm birth and a shortened cervical length in mid-trimester?

Bottom Line

Cerclage reduces incidence of preterm births before 35 weeks' gestation in women with prior preterm birth and a mid-trimester cer-

vical length of less than 15 mm. (LOE = 1b)

Study Design

Randomized controlled trial (nonblinded)

Funding

Foundation

Allocation

Concealed

Setting

Outpatient (specialty)

Synopsis

These authors randomized 302 women with history of preterm birth and a cervix of less than 25 mm in the second trimester of the current singleton gestation to receive cerclage or to a control group. Women were enrolled between 16 and 22 weeks' gestation. Exclusion criteria were fetal anomalies, planned cerclage, maternal-fetal complications that increase the likelihood of an indication for preterm delivery, and acute cervical insufficiency defined as dilatation of 2 cm with visible membranes on speculum examination. Participating sonographers were certified to ensure uniformity of measurements. Allocation was concealed, and treating physicians were masked to assessments of cervical length (though they knew the cervical length had to be less than 25 mm to meet the criteria for study entry). Cerclage was performed no later than gestational week 23. Analysis of all women was by intention to treat with the exception of 1 patient (from the cerclage group), who was excluded from the analysis for lack of outcome data. The primary outcome was preterm birth before 35 weeks' gestation, which was not significantly different between groups except in the planned subgroup analysis among women with a cervical length of less than 15 mm (odds ratio [OR] = 0.23; 95% CI, 0.08-0.66; *P* = .006). Cerclage reduced the incidence of 2 secondary outcomes, birth at less than 24 weeks' (6% vs 14%; *P* = .03; NNT = 13; 95% CI, 7-122) and preterm birth at less than 37 weeks' (45% vs 60%; *P* = .01; NNT= 3.4; 95% CI, 2.6-5.6). The secondary outcome of perinatal death was also statistically significant, although without correction for multiple measurements and with the caveat of 1 unknown outcome that could change the result (9% vs 16%; *P* = .046; NNT = 13; 95% CI not calculable).

REFERENCE

Owen J, Hankins G, Iams JD, et al. Multicenter randomized trial of cerclage for preterm birth prevention in high-risk women with shortened midtrimester cervical length. *Am J Obstet Gynecol.* 2009;201(4):375.e1-e8.

Community-Based Computer-Assisted Motivational Intervention Reduces Repeat Births to Adolescents

Clinical Question

Does community-based computer-assisted motivational intervention (CAMI) for adolescent mothers reduce subsequent births?

Bottom Line

A CAMI reduced rapid subsequent births among adolescent mothers who participated in at least 2 sessions. (LOE = 1b-)

Study Design

Randomized controlled trial (nonblinded)

Funding

Government

Allocation

Concealed

Setting

Population-based

Synopsis

Brief motivational interviewing interventions have been used successfully with teens to reduce substance use and modify dieting behavior. In this study the authors tested a CAMI for adolescent mothers (N = 235, aged 12-18 years) to reduce subsequent births. The study was conducted in Baltimore, Maryland, where the teen birth rate is almost twice the national average. CAMI sessions were initiated within 6 weeks post partum. The CAMI required the teen to answer on a laptop computer questions regarding sexual relationships, contraceptive and condom use intentions, and behaviors. Specially programmed algorithms computed stage of change and produced a printout depicting whether she was at no, low, medium, or high risk for pregnancy and sexually transmitted infections. Counselors (African American paraprofessional women) then conducted a 20-minute motivational interviewing session matched to the teen's stage of change.

CAMI sessions were done every 3 months for 2 years. CAMI sessions were stopped if the teen became pregnant during the study. There were 3 study groups: CAMI alone, CAMI plus home visits every 2 to 4 weeks for parent training and case management, and standard usual care. Repeat birth was not significantly reduced in the CAMI groups after intention-to-treat analysis. However, among teens who completed 2 or more sessions, preterm births were reduced in both CAMI groups (CAMI-only hazard ratio [HR] = 0.19; 95% CI, 0.05-0.69; CAMI-plus HR 0.40; 95% CI, 0.16-0.98).

REFERENCE

Barnet B, Liu J, DeVoe M, Gold MA, Pecukonis E. Motivational intervention to reduce rapid subsequent births to adolescent mothers: a community-based randomized trial. *Ann Fam Med.* 2009;7(5):436-445.