30778597\_PD.txt

Title: Effect of Intravenous Acetaminophen vs Placebo Combined With Propofol or Dexmedetomidine on Postoperative <P 0, 29> Delirium </> Among Older Patients Following Cardiac Surgery: The DEXACET Randomized Clinical Trial.

Publication Type: Journal Article

Journal-Name:JAMA

Journal ID: 7501160

Publication date: 2019/03/12 06:00 [medline]

Importance: Postoperative delirium is common following cardiac surgery and may be affected by choice of analgesic and sedative. Objective: To evaluate the effect of postoperative intravenous (IV) acetaminophen (paracetamol) vs placebo combined with IV propofol vs dexmedetomidine on postoperative <P 0, 29> delirium </> among older patients undergoing cardiac surgery. Design, Setting, and Participants: Randomized, placebo-controlled, factorial clinical trial among 120 patients aged 60 years or older undergoing on-pump coronary artery bypass graft (CABG) surgery or combined CABG/valve surgeries at a US center. Enrollment was September 2015 to April 2018, with follow-up ending in April 2019. Interventions: Patients were randomized to 1 of 4 groups receiving postoperative analgesia with IV acetaminophen or placebo every 6 hours for 48 hours and postoperative sedation with dexmedetomidine or propofol starting at chest closure and continued for up to 6 hours (acetaminophen and dexmedetomidine: n = 29; placebo and dexmedetomidine: n = 30; acetaminophen and propofol: n = 31; placebo and propofol: n = 30). Main Outcomes and Measures: The primary outcome was incidence of postoperative in-hospital <P 0, 29> delirium </> by the Confusion Assessment Method. Secondary outcomes included <P 0, 29> delirium duration </>, <P 0, 29> cognitive decline </>, breakthrough <P 36> analgesia </> within the first 48 hours, and <P 35> ICU and hospital length of stay </>. Results: Among 121 patients randomized (median age, 69 years; 19 women [15.8%]), 120 completed the trial. Patients treated with IV acetaminophen had a significant reduction in <P 0, 29> delirium </> (10% vs 28% placebo; difference, -18% [95% CI, -32% to -5%]; P = .01; HR, 2.8 [95% CI, 1.1-7.8]). Patients receiving dexmedetomidine vs propofol had no significant difference in <P 0, 29> delirium </> (17% vs 21%; difference, -4% [95% CI, -18% to 10%]; P = .54; HR, 0.8 [95% CI, 0.4-1.9]). There were significant differences favoring acetaminophen vs placebo for 3 prespecified secondary outcomes: <P 0, 29> delirium duration </> (median, 1 vs 2 days; difference, -1 [95% CI, -2 to 0]), <P 35> ICU length of stay </> (median, 29.5 vs 46.7 hours; difference, -16.7 [95% CI, -20.3 to -0.8]), and breakthrough <P 36> analgesia </> (median, 322.5 vs 405.3 microg morphine equivalents; difference, -83 [95% CI, -154 to -14]). For dexmedetomidine vs propofol, only breakthrough analgesia was significantly different (median, 328.8 vs 397.5 microg; difference, -69 [95% CI, -155 to -4]; P = .04). Fourteen patients in both the placebo-dexmedetomidine and acetaminophen-propofol groups (46% and 45%) and 7 in the acetaminophen-dexmedetomidine and placebo-propofol groups (24% and 23%) had <P 0> hypotension </>. Conclusions and Relevance: Among older patients undergoing cardiac surgery, postoperative scheduled IV acetaminophen, combined with IV propofol or dexmedetomidine, reduced in-hospital <P 0, 29> delirium </> vs placebo. Additional research, including comparison of IV vs oral acetaminophen and other potentially opioid-sparing analgesics, on the incidence of postoperative delirium is warranted. Trial Registration: ClinicalTrials.gov Identifier: NCT02546765.

30779528\_PD.txt

Title: Bag-Mask Ventilation during Tracheal Intubation of Critically Ill Adults.

Publication Type: Journal Article

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/02/20 06:00 [entrez]

BACKGROUND: Hypoxemia is the most common complication during tracheal intubation of critically ill adults and may increase the risk of cardiac arrest and death. Whether positive-pressure ventilation with a bag-mask device (bag-mask ventilation) during tracheal intubation of critically ill adults prevents hypoxemia without increasing the risk of aspiration remains controversial. METHODS: In a multicenter, randomized trial conducted in seven intensive care units in the United States, we randomly assigned adults undergoing tracheal intubation to receive either ventilation with a bag-mask device or no ventilation between induction and laryngoscopy. The primary outcome was the lowest <P 0> oxygen saturation </> observed during the interval between induction and 2 minutes after tracheal intubation. The secondary outcome was the incidence of <P 0> severe hypoxemia </>, defined as an oxygen saturation of less than 80%. RESULTS: Among the 401 patients enrolled, the median lowest <P 0> oxygen saturation </> was 96% (interquartile range, 87 to 99) in the bag-mask ventilation group and 93% (interquartile range, 81 to 99) in the no-ventilation group (P = 0.01). A total of 21 patients (10.9%) in the bag-mask ventilation group had <P 0> severe hypoxemia </>, as compared with 45 patients (22.8%) in the no-ventilation group (relative risk, 0.48; 95% confidence interval [CI], 0.30 to 0.77). Operator-reported <P 0> aspiration </> occurred during 2.5% of intubations in the bag-mask ventilation group and during 4.0% in the no-ventilation group (P = 0.41). The incidence of new <P 0> opacity </> on chest radiography in the 48 hours after tracheal intubation was 16.4% and 14.8%, respectively (P = 0.73). CONCLUSIONS: Among critically ill adults undergoing tracheal intubation, patients receiving bag-mask ventilation had higher <P 0> oxygen saturations </> and a lower incidence of <P 0> severe hypoxemia </> than those receiving no ventilation. (Funded by Vanderbilt Institute for Clinical and Translational Research and others; PreVent ClinicalTrials.gov number, NCT03026322.).

30786186\_PD.txt

Title: Rivaroxaban for Thromboprophylaxis in High-Risk Ambulatory Patients with Cancer.

Publication Type: Journal Article

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/02/28 06:00 [medline]

BACKGROUND: Ambulatory patients receiving systemic cancer therapy are at varying risk for venous thromboembolism. However, the benefit of thromboprophylaxis in these patients is uncertain. METHODS: In this double-blind, randomized trial involving high-risk ambulatory patients with cancer (Khorana score of >/=2, on a scale from 0 to 6, with higher scores indicating a higher risk of venous thromboembolism), we randomly assigned patients without deep-vein thrombosis at screening to receive rivaroxaban (at a dose of 10 mg) or placebo daily for up to 180 days, with screening every 8 weeks. The primary efficacy end point was a composite of objectively confirmed <P 0> proximal deep-vein thrombosis in a lower limb </>, <P 0> pulmonary embolism </>, <P 0> symptomatic deep-vein thrombosis in an upper limb </> or <P 0> distal deep-vein thrombosis in a lower limb </>, and <P 1> death from venous thromboembolism </> and was assessed up to day 180. In a prespecified supportive analysis involving the same population, the same end point was assessed during the intervention period (first receipt of trial agent to last dose plus 2 days). The primary safety end point was <P 0> major bleeding </>. RESULTS: Of 1080 enrolled patients, 49 (4.5%) had thrombosis at screening and did not undergo randomization. Of the 841 patients who underwent randomization, the primary end point occurred in 25 of 420 patients (6.0%) in the rivaroxaban group and in 37 of 421 (8.8%) in the placebo group (hazard ratio, 0.66; 95% confidence interval [CI], 0.40 to 1.09; P = 0.10) in the period up to day 180. In the prespecified intervention-period analysis, the primary end point occurred in 11 patients (2.6%) in the rivaroxaban group and in 27 (6.4%) in the placebo group (hazard ratio, 0.40; 95% CI, 0.20 to 0.80). <P 0> Major bleeding </> occurred in 8 of 405 patients (2.0%) in the rivaroxaban group and in 4 of 404 (1.0%) in the placebo group (hazard ratio, 1.96; 95% CI, 0.59 to 6.49). CONCLUSIONS: In high-risk ambulatory patients with cancer, treatment with rivaroxaban did not result in a significantly lower incidence of <P 0> venous thromboembolism </> or <P 1> death due to venous thromboembolism </> in the 180-day trial period. During the intervention period, rivaroxaban led to a substantially lower incidence of such events, with a low incidence of <P 0> major bleeding </>. (Funded by Janssen and others; CASSINI ClinicalTrials.gov number, NCT02555878.).

30786187\_PD.txt

Title: Once-Daily Plazomicin for Complicated Urinary Tract Infections.

Publication Type: Equivalence Trial

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/02/28 06:00 [medline]

BACKGROUND: The increasing multidrug resistance among gram-negative uropathogens necessitates new treatments for serious infections. Plazomicin is an aminoglycoside with bactericidal activity against multidrug-resistant (including carbapenem-resistant) Enterobacteriaceae. METHODS: We randomly assigned 609 patients with complicated urinary tract infections (UTIs), including acute pyelonephritis, in a 1:1 ratio to receive intravenous plazomicin (15 mg per kilogram of body weight once daily) or meropenem (1 g every 8 hours), with optional oral step-down therapy after at least 4 days of intravenous therapy, for a total of 7 to 10 days of therapy. The primary objective was to show the noninferiority of plazomicin to meropenem in the treatment of complicated UTIs, including acute pyelonephritis, with a noninferiority margin of 15 percentage points. The primary end points were composite <P 0> cure </> ( <P 0> clinical cure and microbiologic eradication </>) at day 5 and at the test-of-cure visit (15 to 19 days after initiation of therapy) in the microbiologic modified intention-to-treat population. RESULTS: Plazomicin was noninferior to meropenem with respect to the primary efficacy end points. At day 5, composite <P 0> cure </> was observed in 88.0% of the patients (168 of 191 patients) in the plazomicin group and in 91.4% (180 of 197 patients) in the meropenem group (difference, -3.4 percentage points; 95% confidence interval [CI], -10.0 to 3.1). At the test-of-cure visit, composite <P 0> cure </> was observed in 81.7% (156 of 191 patients) and 70.1% (138 of 197 patients), respectively (difference, 11.6 percentage points; 95% CI, 2.7 to 20.3). At the test-of-cure visit, a higher percentage of patients in the plazomicin group than in the meropenem group were found to have <P 0> microbiologic eradication </>, including eradication of Enterobacteriaceae that were not susceptible to aminoglycosides (78.8% vs. 68.6%) and Enterobacteriaceae that produce extended-spectrum beta-lactamases (82.4% vs. 75.0%). At late follow-up (24 to 32 days after initiation of therapy), fewer patients in the plazomicin group than in the meropenem group had <P 0> microbiologic recurrence </> (3.7% vs. 8.1%) or <P 0> clinical relapse </> (1.6% vs. 7.1%). Increases in serum <P 0> creatinine </> levels of 0.5 mg or more per deciliter (>/=40 mumol per liter) above baseline occurred in 7.0% of patients in the plazomicin group and in 4.0% in the meropenem group. CONCLUSIONS: Once-daily plazomicin was noninferior to meropenem for the treatment of complicated UTIs and acute pyelonephritis caused by Enterobacteriaceae, including multidrug-resistant strains. (Funded by Achaogen and the Biomedical Advanced Research and Development Authority; EPIC ClinicalTrials.gov number, NCT02486627.).

*30786196\_PD.txt*

*Title: Plazomicin for Infections Caused by Carbapenem-Resistant Enterobacteriaceae.*

*Publication Type: Multicenter Study*

*Journal-Name:The New England journal of medicine*

*Journal ID: 0255562*

*Publication date: 2019/02/28 06:00 [medline]*

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30802196\_PD.txt

Title: Comparison of sufentanil-midazolam and sevoflurane for anesthesia induction in children undergoing cardiac surgery by real-time <P 0> hemodynamic </> and <P 0> cardiac </> efficiency monitoring: A prospective randomized study.

Publication Type: Randomized Controlled Trial

Journal-Name:The heart surgery forum

Journal ID: 100891112

Publication date: 2019/02/26 06:00 [entrez]

Background Intravenous sufentanil-midazolam and inhalational sevoflurane are widely used for anesthetic induction in children undergoing cardiac surgery. However, knowledge about their effects on hemodynamics and cardiac efficiency remains limited due largely to the lack of direct monitoring method. We used minimally invasive technique pressure recording analytical method (PRAM) to directly monitor <P 0> hemodynamics </> and <P 0> cardiac </> efficiency and compared the effects of the two anesthetic regimens in children undergoing ventricular septal defect repair. Methods Forty-Four children (2.3+/-0.9 years) were randomly divided into two groups to receive either intravenous sufentanil (1 mug/kg) and midazolam (0.2 mg/kg) (Group SM) or 2.0 minimal alveolar concentration (MAC) sevoflurane (Group S) to complete induction after sedation was obtained with 2.0 MAC sevoflurane. Systemic <P 0> hemodynamic </> data recorded by PRAM included <P 0> heart rate (HR) </>, <P 0> systolic (SBP) {and mean (MBP)} blood pressure </>, <P 0> stroke volume </> index (SVI), <P 0> cardiac </> index (CI), <P 0> systemic vascular resistance </> index (SVRI), the maximal slope of <P 0> systolic upstroke </> (dp/dtmax) and <P 0> cardiac cycle </> efficiency (CCE) after sedation obtained, 1, 2, 5 min after induction achieved, 1, 2, 5 and 10 min after intubation. Results <P 0> heart rate (HR) </>, <P 0> systemic vascular resistance </> index (SVRI) showed a decrease in Group SM but an increase in Group S (Ptime\*group<0.0001) in the study period. <P 0> Stroke volume </> index (SVI) and <P 0> cardiac cycle </> efficiency (CCE) showed an increase in Group SM but a decrease in Group S (Ptime\*group<0.0001). <P 0> Systolic (SBP) {and mean (MBP)} blood pressure </>, and <P 0> cardiac </> index (CI) were related to time after polynomial transformation, and showed an increase after intubation in Group SM but a decrease in Group S (Ptime2\*group<0.0001). Conclusion PRAM provides meaningful and direct monitoring of hemodynamics and cardiac efficiency during the dynamic period of anesthetic induction in children undergoing cardiac surgery. As compared to inhalational sevoflurane, intravenous sufentanil-midazolam exerts more favorable effects on <P 0> systemic hemodynamics </> and <P 0> cardiac </> efficiency during anesthetic induction in this group of patients.

30811909\_PD.txt

Title: A Randomized Trial of Lymphadenectomy in Patients with Advanced Ovarian Neoplasms.

Publication Type: Multicenter Study

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/03/08 06:00 [medline]

BACKGROUND: Systematic pelvic and paraaortic lymphadenectomy has been widely used in the surgical treatment of patients with advanced ovarian cancer, although supporting evidence from randomized clinical trials has been limited. METHODS: We intraoperatively randomly assigned patients with newly diagnosed advanced ovarian cancer (International Federation of Gynecology and Obstetrics stage IIB through IV) who had undergone macroscopically complete resection and had normal lymph nodes both before and during surgery to either undergo or not undergo lymphadenectomy. All centers had to qualify with regard to surgical skills before participation in the trial. The primary end point was <P 1> overall survival </>. RESULTS: A total of 647 patients underwent randomization from December 2008 through January 2012, were assigned to undergo lymphadenectomy (323 patients) or not undergo lymphadenectomy (324), and were included in the analysis. Among patients who underwent lymphadenectomy, the median number of removed <P 0> nodes </> was 57 (35 pelvic and 22 paraaortic nodes). The median <P 1> overall survival </> was 69.2 months in the no-lymphadenectomy group and 65.5 months in the lymphadenectomy group (hazard ratio for death in the lymphadenectomy group, 1.06; 95% confidence interval [CI], 0.83 to 1.34; P = 0.65), and median <P 0, 1> progression-free survival </> was 25.5 months in both groups (hazard ratio for progression or death in the lymphadenectomy group, 1.11; 95% CI, 0.92 to 1.34; P = 0.29). Serious postoperative <P 38> complications </> occurred more frequently in the lymphadenectomy group (e.g., incidence of repeat laparotomy, 12.4% vs. 6.5% [P = 0.01]; <P 1> mortality </> within 60 days after surgery, 3.1% vs. 0.9% [P = 0.049]). CONCLUSIONS: Systematic pelvic and paraaortic lymphadenectomy in patients with advanced ovarian cancer who had undergone intraabdominal macroscopically complete resection and had normal lymph nodes both before and during surgery was not associated with longer <P 1>(E1) overall or <P 0, 1> progression-free survival </> than no lymphadenectomy and was associated with a higher incidence of postoperative <P 38> complications </>. (Funded by Deutsche Forschungsgemeinschaft and the Austrian Science Fund; LION ClinicalTrials.gov number, NCT00712218.).

30813125\_PD.txt

Title: Observation of the curative effect of device-guided rehabilitation on <P 0> respiratory function </> in stable patients with chronic obstructive pulmonary disease.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/03/07 06:00 [medline]

BACKGROUND: Chronic obstructive pulmonary disease (COPD) is a serious lung disease for individuals in middle age and especially in old people. The study was aimed to observe the curative effect of device-guided rehabilitation on respiratory functions in stable COPD patients. METHODS: Sixty-seven stable COPD patients were enrolled and assigned to the experiment group (n = 36) and the control group (n = 31). The conventional pulmonary rehabilitation treatments, including pursed lips breathing (PLB) and abdominal breathing training, were applied in the control group. Respiratory muscle training of the experiment group was performed using the respiratory endurance training device combined with traditional techniques. Both groups were assessed by [T 6-minute <P 25> walk </> test (6MWT)], [T <P 0> chronic obstructive pulmonary disease (COPD) </> assessment test (CAT)], [T <P 0> body mass index </>, <P 0> airflow obstruction </>, <P 0> dyspnea </>, and <P 0, 25> exercise capacity </> (BODE) index]. Besides, the <P 0> pulmonary function </> (FVC</>%, FEVl</>%) were measured at 6 months before and after treatment. RESULTS: After treatment, the [T 6-minute <P 25> walk </> test (6MWT)], [T <P 0> chronic obstructive pulmonary disease (COPD) </> assessment test (CAT)], [T <P 0> body mass index </>, <P 0> airflow obstruction </>, <P 0> dyspnea </>, and <P 0, 25> exercise capacity </> (BODE) index] were significantly increased compared with pre-treatment in both groups (P < .01), but not FVC</>% and FEVl</>%. Compared with the control group, the combination therapy in the experiment group could significantly improve the 6MWT (P = .0094), CAT (P = .0071) and BODE index (P = .0064) as well as the changes of 6MWT (P < .01), CAT (P < .01), and BODE index (P < .01) before and after treatment. CONCLUSIONS: The traditional respiratory training combined with device-guided pulmonary rehabilitation can improve the <P 0> respiratory muscle function </> and <P 0> athletic ability </> in stable COPD patients.

30813149\_PD.txt

Title: Oral glutamine supplements reduce concurrent chemoradiotherapy-induced esophagitis in patients with advanced non-small cell lung cancer.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/03/12 06:00 [medline]

BACKGROUND: Complications related to concurrent chemoradiotherapy (CCRT) such as acute radiation-induced esophagitis (ARIE) may cause significant morbidity and unplanned treatment delays in patients with advanced non-small cell lung cancer (NSCLC). We designed a prospective randomized study to assess the impact of glutamine (GLN) supplementation in preventing CCRT-induced <P 38> toxicities </> of advanced NSCLC patients. METHODS: From September 2014 to September 2015, 60 patients diagnosed with NSCLC were included to the study. Thirty patients (50%) received prophylactic powdered GLN orally at a dose of 10 g/8 h. The prescribed radiation dose to the planning target volume was 30 Gy in 2-Gy fractions. The endpoints were radiation-induced <P 0> esophagitis </>, <P 0> mucositis </>, <P 0> body weight </> loss, <P 1> overall survival </> and <P 0, 1> progression-free survival </>. RESULTS: The 60 patients with NSCLC included 42 men and 18 women with a mean age +/- standard deviation of 60.3 years +/- 18.2 (range, 44-78 years).At a median follow-up of 26.4 months (range 10.4-32.2), all patients <P 32> tolerated </> GLN well. A administration of GLN was associated with a decrease in the incidence of grade 2 or 3 acute radiation-induced <P 0> esophagitis </> (ARIE) (6.7% vs 53.4% for Gln+ vs Gln-; P = .004). GLN supplementation appeared to significantly delay acute radiation-induced <P 0> esophagitis </> (ARIE) onset for 5.8 days (18.2 days vs 12.4 days; P = .027) and reduced incidence of <P 0> weight </> loss (20% vs 73.3%; P = .01). DISCUSSION: Our study suggests a beneficial effect of oral glutamine supplementation for the prevention from radiation-induced <P 0> injury </> and <P 0> body weight </> loss in advanced NSCLC patients who receiving CCRT.

30813155\_PD.txt

Title: A randomized trial of trigger point dry needling versus sham needling for chronic tension-type headache.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/03/12 06:00 [medline]

BACKGROUND: In this randomized, double-blind, parallel-group trial, we aimed to explore the effectiveness of trigger point dry needling in patients with chronic tension-type headache in reducing <P 0>(S1) headache <P 0> frequency,<P 0> intensity <P 0> and duration </>, and improvement of <P 30> health-related quality of life </>. METHODS: The 168 patients in 2 neurology clinics with chronic tension-type headache. The participants were randomly assigned to one of two treatment groups for dry needling or sham dry needling, delivered in 3 sessions a week for 2 weeks. The 160 patients fulfilled the study requirements. The dry needling was applied in active trigger points located in the musculature of the head and the neck. The patients received dry needling using sterile stainless-steel acupuncture needles of 0.25 x 40 mm and 0.25 x 25 mm dimensions. The sham dry needling procedure was applied into the adipose tissue located at any area where an active trigger point was absent. The primary outcome measurement was the <P 0> headache intensity </>. Secondary outcomes were frequency and <P 0>(E1) duration of <P 0> headache </>, and <P 30> quality of life </>, assessed by the Short Form-36. All outcomes were measured at baseline, at the end of 2-week, and 1-month follow-up period. RESULTS: In the dry needling group, <P 0>(E1) intensity of, {frequency and} <P 0> duration of <P 0> headache </>, and the scores of [T Short Form-36] subscales were significantly improved after treatment (P < .05). In the dry needling group, all the effect sizes for headache variables were large. CONCLUSIONS: The results of this clinical trial suggest that trigger point dry needling in patients with chronic tension-type headache is effective and safe in reducing <P 0>(S1) headache <P 0> intensity <P 0>, {frequency} and duration </>, and increasing <P 30> health-related quality of life </>. TRIAL REGISTRATION: Clinical Trials NCT03500861.