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This series is coordinated by Sumi Sexton, MD, Associate Deputy Editor.

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Sertraline Reduces Risk of Depression in Adults After Traumatic Brain Injury

Clinical Question

Does sertraline (Zoloft) reduce the risk of depression in adults following traumatic brain injury (TBI)?

Bottom Line

This study found that sertraline is more effective than placebo (number needed to treat = 6) in preventing the onset of a major depressive disorder in adults following a TBI. This study included patients with mild, moderate, and severe TBI. (Level of Evidence = 1b-)

Synopsis

Depressive disorders are a common and disabling complication after TBI. These investigators identified patients (N = 94) 18 to 85 years of age with a diagnosis of closed (nonpenetrating) TBI according to Glasgow Coma Scale (GCS) scores and computed tomographic scans taken on admission. Of these 94 patients, 69 (73%) had moderate TBI (GCS score 9 to 12), 16 (17%) had mild TBI (GCS score > 12), and nine (10%) had severe TBI (GCS score < 9). Eligibility criteria included complete recovery of posttraumatic amnesia within four weeks of the injury and absence of ongoing depression. All patients randomly received (concealed allocation assignment) sertraline—titrated at 25 mg per day for five days, 50 mg per day for five days, and 100 mg per day thereafter—or matched placebo. The primary outcome was time to onset of depressive disorder as determined by

standard diagnostic criteria. Individuals masked to treatment group assignment assessed all outcomes. Complete follow-up occurred for 84% of patients at 24 weeks.

Using intention-to-treat analysis, significantly fewer patients in the sertraline group developed symptoms consistent with major depression than did those in the placebo group (number needed to treat = 6; 95% confidence interval, 3.1 to 71.7). Adverse events, including dry mouth, diarrhea, and sexual dysfunction, were mild but more common in the sertraline group.

Study design: Randomized controlled trial (double-blinded)

Funding source: Government

Allocation: Concealed

Setting: Outpatient (specialty)

Reference: Jorge RE, Acion L, Burin DI, Robinson RG. Sertraline for preventing mood disorders following traumatic brain injury: a randomized clinical trial. *JAMA Psychiatry*. 2016;73(10):1041-1047.

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Brief Interventions for Weight Management in Kids Are Not Effective

Clinical Question

Should children and adolescents be screened for body mass index (BMI) and be given brief counseling if overweight?

Bottom Line

Calculating the BMI of children and adolescents in primary care practices and counseling those who are overweight is ineffective to reduce BMI in children over several years of follow-up. (Level of Evidence = 1a)

Synopsis

These investigators searched five databases, including the Cochrane Central Library, as well as reference lists of retrieved studies and review articles, to identify 10 randomized studies and two quasi-experimental studies that evaluated the effect of brief interventions to reduce BMI in children between the ages of two years and 18 years. They looked at any primary care weight-management interventions (e.g., lifestyle modification education, BMI feedback and lifestyle counseling, motivational interviewing). Two reviewers independently ►

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selected articles and abstracted the data. The quality of the research was not good. Brief interventions produced a very small reduction in the BMI z score, which is the measure of the relative weight adjusted for the child's age and sex (effect size compared with usual care = -0.04 ; 95% confidence interval, -0.08 to -0.01), with good agreement across the studies. A change of 0.5 to 0.6 is necessary to be sure of a clear reduction in fat and associated health benefit. Body satisfaction scores were similar between treatment group and control group patients, as were child- and parent-reported quality-of-life and self-worth scores, although there was significant heterogeneity among these results. Adverse effects were not measured in most studies.

Study design: Meta-analysis (randomized controlled trials)

Funding source: Self-funded or unfunded

Setting: Various (meta-analysis)

Reference: Sim LA, Lebow J, Wang Z, Koball A, Murad MH. Brief primary care obesity interventions: a meta-analysis. *Pediatrics*. 2016;138(4):e20160149.

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Active Surveillance for Localized Prostate Cancer: No Increased Mortality, but Higher Rates of Clinical Progression

Clinical Question

What is the best approach to the management of localized prostate cancer?

Bottom Line

This landmark study compared active surveillance with radical prostatectomy or radiation therapy for patients with T1c or T2 prostate cancer. The benefits of active surveillance include avoiding radical therapy in one-half of the patients, with no effect on disease-specific survival or all-cause survival. The potential harms include a greater risk of metastatic disease (three additional cases per 1,000 person-years, corresponding to three additional cases for 100 men followed up for 10 years) and a greater likelihood of clinical progression. An accompanying study (*N Engl J Med*. 2016;375(15):1425-1437) discusses the effects on quality of life and complications of treatment. (Level of Evidence = 1b)

Synopsis

Clinically localized prostate cancer is defined as stage T1c or T2, and is confined to the prostate gland. In this study, 82,429 British men 50 to 69 years of age had a prostate-specific antigen (PSA) test. Of those, 2,664 had grade T1c or T2 cancer, and 1,643 agreed to be randomized to one of three groups: radical prostatectomy, radiotherapy, or a program of active surveillance. Active surveillance consisted of frequent PSA tests (every three months in the first year and every six to 12 months after that), with a rise of 50% or more triggering an evaluation for possible biopsy and treatment, if indicated. Approximately 80% of men assigned to surgery or radiotherapy received the assigned treatment during the first year following randomization.

In the active surveillance group, there was a steady increase in the percentage of men who received radiotherapy, prostatectomy, or another treatment with curative intent, from 20% at year 2, to 40% at year 5, to slightly more than 50% at year 10. There was no difference between groups in mortality due to prostate cancer, prostate cancer-specific survival at five or 10 years, or all-cause mortality. However, there was a greater likelihood of developing metastatic disease in the active surveillance group, with approximately three more metastatic cancers detected per 1,000 person-years than in the surgery or radiotherapy groups ($P = .004$). Clinical progression (defined as progression to T3 or T4 disease, urinary or rectal complications, or the use of androgen deprivation therapy) was also more common in the active surveillance group, with approximately 13 additional patients progressing per 1,000 person-years. Stratification of patients by age, PSA result, Gleason score, or stage at diagnosis did not affect the results.

Study design: Randomized controlled trial (single-blinded)

Funding source: Government

Allocation: Uncertain

Setting: Outpatient (specialty)

Reference: Hamdy FC, Donovan JL, Lane JA, et al.; ProtecT Study Group. 10-year outcomes after monitoring, surgery, or radiotherapy for localized prostate cancer. *N Engl J Med*. 2016;375(15):1415-1424.

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