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Drug Information News Letter
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Idiopathic Intracranial Hypertension May Double Cardiovascular Risk

Idiopathic intracranial hypertension (IIH) in women appears to be associated with an increased cardiovascular risk. This is a landmark study in that the possible long-term sequelae of idiopathic intracranial hypertension have not really been considered before. This results show that patients with idiopathic intracranial hypertension have double the risk of future cardiovascular events compared to controls even after adjusting for body mass index (BMI). "This implies that idiopathic intracranial hypertension is actually a systemic metabolic condition, and that patients need to have their cardiovascular risk strictly managed."

Patients are typically young and female, and more than 90% are obese. The incidence and economic burden of idiopathic intracranial hypertension are raising in line with global obesity figures. Management focuses on preserving vision and reducing headache morbidity, but long-term consequences of having the condition are unknown.

Noting that IIH has recently been linked to a unique profile of androgen excess, another key driver of increased cardiovascular risk, the researchers conducted the current study to try to define cardiometabolic risk in these patients, independent of BMI.

They analyzed data over a 28-year period from The Health Improvement Network (THIN), an anonymized, nationally representative electronic medical records database in the UK, and identified 2760 female patients with IIH (mean age 32 years, 60% obese) who were each matched with up to 10 controls by BMI and age. A total of 27,125 controls were included in the study.

Results showed that women with IIH had higher absolute risks for all cardiovascular outcomes vs controls. Hazard ratios were 2.10 for all cardiovascular events, 1.97 for heart failure, 1.94 for ischemic heart disease, 2.27 for stroke/transient ischemic attack, 1.30 for type 2 diabetes, and 1.55 for hypertension. All of the findings were statistically significant.

Data also showed that the prevalence of IIH in female patients tripled between 2005 and 2017, from 26 to 79 per 100,000 women, with rates increasing markedly in individuals with BMI over 30.

The findings are the first indication that morbidity in this condition may extend beyond the typically considered areas of visual loss and chronic headaches, they add.

The investigators acknowledge that the predominant occurrence of obesity in patients with IIH may be expected to increase the cardiovascular risk, but in this study the increased risk was seen despite matching for BMI and age and controlling for other important covariates, including migraine (which can also be linked to increased cardiovascular risk).

"These are mainly young women and so we have the opportunity to intervene early to reduce their raised cardiovascular risk with weight modification, lifestyle advice on diet, quitting smoking and taking exercise, and close monitoring and treatment of lipids, blood pressure, and blood sugar levels."

Noting that weight loss is a complex issue that requires specialist management and support, health professionals have to do more to encourage these patients to seek medical advice, get help with weight management, and engage with specialist weight loss services.

JAMA Neurol. doi:10.1001/jamaneurol.2019.1812

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New Drug Review: Spravato

In March, the FDA approved intranasal esketamine (Spravato, Janssen), when used in conjunction with an oral antidepressant, for treatment of depression in adults who have not benefitted from other antidepressant medications. Esketamine is the s-enantiomer of racemic ketamine and functions as an N-methyl-D-aspartate (NMDA) receptor antagonist that leads to alleviation of treatment-resistant depression (TRD).1

Efficacy

Esketamine was evaluated in two phase 3 randomized double-blind multicenter placebo-controlled trials. In one trial, patients meeting DSM-V criteria for TRD (defined as treatment with at least two different antidepressants trialed for adequate dose and duration) were randomized to receive flexible dose (56 mg or 84 mg) intranasal esketamine plus an oral antidepressant or intranasal placebo plus an oral antidepressant. Esketamine and oral antidepressant was significantly better at controlling depression; a significant reduction (-4) in the change from baseline score in the Montgomery-Asberg Depression Rating Scale (MADRS) at week 4.2 In the second trial, patients who were responders or remitters to esketamine after at least 16 weeks of therapy were randomized to either continue receiving intranasal treatment and an oral antidepressant or placebo and an oral antidepressant for long-term variable duration. The primary efficacy measure was time to relapse. Both responder and remitter patients experienced a statistically significant longer time to relapse with esketamine compared to the placebo.3

Safety

The most common adverse events were dissociation (41%), dizziness (29%), nausea (28%), sedation (23%), vertigo (23%), headache (20%), dysgeusia (19%), hypoesthesia (18%), lethargy (11%), and increased blood pressure (10%). Drug-related side effects could affect driving; patients should not drive or operate heavy machinery until the next day, after a restful sleep.

Geriatric use of esketamine was supported by data from clinical trials. No significant differences in safety were observed between the 65 and older group and younger groups.

Physical dependence is reported with prolonged use of large doses of ketamine; no withdrawal symptoms were reported with recommended esketamine use up to 4 weeks after discontinuation. However, dependence may occur in patients who abuse esketamine or take doses larger than recommended.

Dosing

Esketamine induction phase dosing is 56 mg intranasally on day 1, then twice weekly administration of 56 mg or 84 mg weeks 1 through 4. During weeks 5 through 8 of the maintenance phase, patients are administered 56 mg or 84 mg intranasally once weekly. During weeks 9 and onwards, patients are maintained at 56 mg or 84 mg intranasally once weekly or once every 2 weeks.4

A healthcare provider must administer this drug in a clinic. The patient must remain for at least 2 hours and have prearranged transportation home. Patients must also enroll in the risk evaluation and mitigation strategy program. Blood pressure should be monitored before and after treatment. If blood pressure is under 140/90 mmHg, consider waiting for blood pressure to fall before administering esketamine. After administration, blood pressure should be monitored for 2 hours. If blood pressure remains elevated 40 minutes postdose, refer patient for immediate emergency care.

Patients using a nasal decongestant or nasal corticosteroid should administer medications at least 1 hour before esketamine use. Because nausea and vomiting are common side effects, patients should avoid eating food for at least 2 hours and avoid drinking liquids for at least 30 minutes before administration.

Dose adjustments are not recommended for patients with renal or hepatic insufficiency. Use of esketamine is not recommended in patients with Child-Pugh C hepatic dysfunction.

Spravato. Janssen Pharmaceuticals, Inc; 2019. Available at https://bit.ly/2Yo7fFA.

CLINICAL CONNECTION

Is muscular fitness associated with future health?

Muscular fitness is a valuable indicator for monitoring child and adolescent health. Despite this, recent evidence shows a decline in muscular fitness in school-age youth. To support the development of health-promoting strategies, it is important to monitor fitness levels in children and to quantify associations with health parameters later in life. García-Hermoso et al. performed a meta-analysis of articles that examined healthy children aged 3–18 years with muscular fitness assessed at baseline and a follow-up period of ≥1 year. They included 30 studies and found significant correlations with moderate–large ($P<0.05$) effect sizes between muscular fitness at baseline and parameters for obesity (body mass index, skinfold thickness), cardio-metabolic health (homeostasis model assessment estimated insulin resistance, triglycerides, cardiovascular disease risk score) and bone mineral density at follow-up. They conclude that a negative association exists between muscular fitness in childhood/adolescence and adiposity and cardio-metabolic parameters in later life, together with a positive association for bone health.

García-Hermoso et al. 2019 Sports Medicine doi: 10.1007/s40279-019-01098-6

CASE DISSECTION:

A Lady With Breast Fold Skin Rash

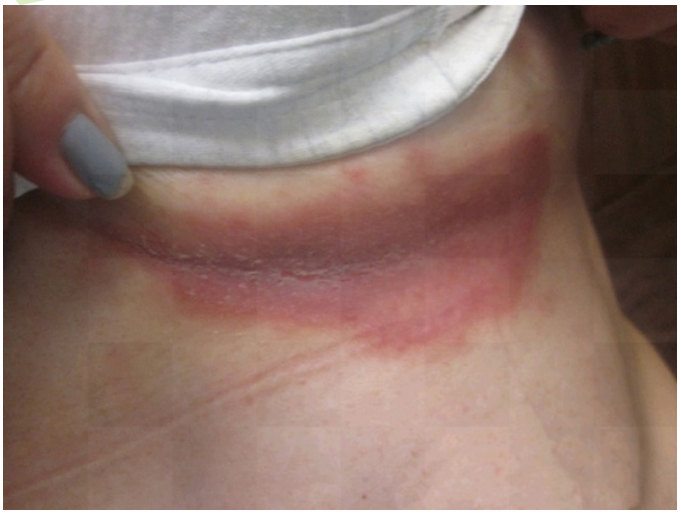
A 32-year-old lady complained about itching in the breast fold and armpit for a month, followed by offensive odour with burning sensation and red patch on her axilla and breast fold. There is no similar skin problem among her family members and there is no domestic animal at home neither.

1. What is the clinical diagnosis?
   - A. Irritant or allergic contact dermatitis
   - B. Intertrigo
   - C. Seborrheic dermatitis
   - D. Inverse psoriasis
2. What investigations should be performed in this patient?
   1. A swab for bacterial culture
   2. A scraping for fungi microscopy and culture
   3. Skin biopsy
   4. Wood's light examination
3. The following treatment is appropriate for this patient EXCEPT?

A. Patient education such as keeping the skin folds dry, weight reduction, zinc oxide to reduce skin fold friction etc.

B. Median to potent corticosteroids cream

C. Control excessive sweating by use of anti-perspiration agent.



D. Use of topical or systemic antimicrobial agents as well as low-potency corticosteroids cream

Discussion

Intertrigo is a common inflammatory condition affecting opposing skin surfaces, which is caused by a combination of infections, mechanical and environmental factors. Infectious and inflammatory causes are common in intertrigo. A swab for bacterial culture and scraping for fungi microscopy may help determine the exact causes of intertrigo, whereas Wood's light examination can be used to identify infection such as erythrasma. Unless in treatment-resistant cases, skin biopsy is not necessary for most patients. Treatment of intertrigo includes removal of predisposing factors and the appropriate use of topical or systemic antimicrobial drugs guided by the culture result of the infection. Potent steroids should be avoided in the flexural area for developing striae at risk.

STAFF PUBLICATIONS

1. Sundeep Mupparaju, Vidyadhara Suryadevara, Sailaja Yallam, Sandeep Doppalapudi, Sasidhar Reddyvallam LC, Ramu Anne. Formulation and Evaluation of Dolutegravir Sodium Solid Dispersions and Fast Dissolving Tablets Using Poloxamer-188 and Jack Fruit Seed Starch as Excipients. EMBASE, Google Scholar, Elsevier Products, EBSCO, SCImago (SJR), Index Copernicus

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