



Choice of anticoagulant for patients with atrial fibrillation and severe chronic kidney disease (September 2024)

Patients with atrial fibrillation (AF) and severe chronic kidney disease (CKD) face increased risks of bleeding and thromboembolism; the optimal anticoagulant in this setting is uncertain. In a clinical database study of nearly 7000 nondialysis-dependent adults with AF and severe CKD, Apixaban use was associated with a lower risk of major bleeding than Rivaroxaban or Warfarin use, while rates of stroke/systemic embolism and death were similar among the three anticoagulants. This study and other observational data support use of Apixaban as the preferred anticoagulant for patients with AF and severe CKD. [1]

Epinephrine nasal spray for anaphylaxis (August 2024)

Epinephrine is the first-line treatment for anaphylaxis and should be given as soon as anaphylaxis is recognized, but needle phobia leads to delayed use of autoinjectors. An epinephrine nasal spray (neffy [brand name]) was approved by the US Food and Drug Administration in August 2024 for use in children and adults weighing ≥ 30 kg (≥ 66 lbs) and should be available later this year. The device contains a single dose of 2 mg that is sprayed into one nostril and provides comparable epinephrine blood levels to those achieved with autoinjectors. It is anticipated that needle-free administration will help alleviate barriers to rapid treatment. [2]



References:

1. Atrial fibrillation in adults: Use of oral anticoagulants (September 2024), accessed online via uptodate , cited on 2nd October 2024.
2. Prescribing epinephrine for anaphylaxis self-treatment (August 2024), accessed online via uptodate , cited on 2nd October 2024.
3. تعليمات صادرة عن المؤسسة العامة للغذاء و الدواء (September 2024), accessed online via www.jfda.jo.com, cited on 2nd October 2024.
4. Immunizations during pregnancy (August 2024), accessed online via uptodate, cited on 2nd October 2024.

تعميم صادر عن المؤسسة العامة للغذاء و الدواء (26/9/2024)

إستنادا إلى نتائج تقييم دراسات السمية التي أجرتها شركة نوفارتس بشأن المستحضر الصيدلاني (Tegretol 100mg/5ml Oral suspension) ، فقد خلصت النتائج إلى أن كمية المادة غير الفعالة Propylene Glycol و المستخدمة في التركيبة غير مدعومة بدراسات تقييم السمية للمرضى الذين تقل أعمارهم عن 4 أسابيع. بناء عليه، يرجى من العاملين لديكم الإلتزام بقرار المؤسسة العامة للغذاء و الدواء بعدم اعتماد الفئة العمرية (حديثي الولادة الذين تقل أعمارهم عن 4 أسابيع للأطفال مكتملي النمو، أو 44 أسبوعا بعد الحمل للأطفال الخدج)، وذلك لأن التركيبة تحتوي على تركيز من مادة Propylene Glycol أعلى من الحد المسموح به للمواليد الجدد، و الذي يبلغ (1mg/kg/day) . و بالتالي: فإن الفوائد المرجوة من هذه التركيبة لم تعد تفوق المخاطر المرتبطة بها. لذا، يرجى التوقف عن استخدام هذا الدواء لهذه الفئة العمرية، و اللجوء إلى بدائل علاجية ملائمة و بحسب ما تتطلبه الحالة المرضية. [3]

RSV vaccination in pregnancy and risk of preterm birth (August 2024)

Respiratory syncytial virus (RSV) infection is a major cause of morbidity and mortality in infants. Maternal vaccination with the inactivated nonadjuvanted recombinant RSV vaccine (RSVPreF [Abrysvo (brand name)]) and/or neonatal immunoprophylaxis with nirsevimab can reduce this risk. While randomized trials have established the vaccine's safety and efficacy, a trend toward an increased risk of preterm birth was observed. Now, an observational study including nearly 3000 pregnant people has reported those who were vaccinated with RSVPreF had similar rates of preterm birth as those who were not vaccinated. As RSV season approaches, we continue to counsel patients regarding the safety and efficacy of one-time maternal vaccination in pregnancies between 32 0/7 and 36 6/7 weeks of gestation expected to deliver during RSV season and not previously vaccinated. [4]

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Investigational once-weekly basal insulin therapy (insulin efsitora) for diabetes management (October 2024)

Insulin efsitora alfa is an investigational, ultra-long-acting insulin. In a trial comparing once-weekly insulin efsitora with once-daily insulin degludec in 928 insulin-naïve adults with type 2 diabetes, mean change in A1C after 52 weeks was similar in both groups (-1.26 and -1.17 percentage points, respectively). Clinically significant (glucose <54 mg/dL [<3 mmol/L]) or severe hypoglycemia was infrequent and did not differ between treatments. In a parallel trial comparing insulin efsitora with insulin degludec in 692 adults with type 1 diabetes, the mean change in A1C after 26 weeks was comparable between groups (-0.51 and -0.56 percentage points, respectively). More participants in the efsitora group experienced severe hypoglycemia (10 versus 3 percent with degludec). Additional trials will help inform the potential clinical utility of insulin efsitora in the treatment of type 1 and type 2 diabetes.[1]

Mineralocorticoid receptor antagonists for heart failure with preserved ejection fraction (September 2024)

The role of **mineralocorticoid receptor antagonists (MRA)** in the treatment of heart failure with preserved ejection fraction (HFpEF) has been unclear. In a recent **randomized trial in over 6000 patients with heart failure (HF) and left ventricular ejection fraction ≥ 40 percent**, patients receiving the MRA finerenone had a lower rate of acute HF episodes than those receiving placebo over a median of 32 months. Though the effect on worsening HF was small, these results are consistent with those previously reported from a controversial trial of spironolactone. In patients receiving optimal therapy with a diuretic and a sodium-glucose co-transporter 2 inhibitor with or without semaglutide and who have persistent New York Heart Association class II to III HF symptoms, we now suggest adding an MRA.[2]

References:

1. General principles of insulin therapy in diabetes mellitus (October 2024), accessed online via uptodate, cited on 2nd October 2024.
2. Treatment and prognosis of heart failure with preserved ejection fraction (September 2024), accessed online via uptodate, cited on 2nd October 2024.
3. Seasonal influenza in nonpregnant adults: Treatment (September 2024), accessed online via uptodate, 3d October 2024.
4. Management of acute moderate and severe traumatic brain injury (August 2024), accessed online via uptodate, cited on 3d October 2024.

Antiviral therapy for severe influenza (September 2024)

Many observational studies have suggested a clinical benefit (including mortality reduction) with antiviral therapy for severe influenza when it is started as soon as possible after hospitalization; data from randomized controlled trials are limited. In a systematic review and network meta-analysis that included three randomized trials in hospitalized patients with severe influenza, treatment with **oseltamivir or peramivir reduced the duration of hospitalization** (mean reductions of 1.63 and 1.73 days, respectively, compared with placebo or standard care), but there was low certainty in the outcomes because of imprecision and risk of bias. Despite the limitations of the trial data, **we continue to suggest treatment with oseltamivir (administered orally) for hospitalized patients with influenza**; IV peramivir is an alternative regimen.[3]

Ceftriaxone for pneumonia prevention in ventilated patients with acute traumatic brain injury (August 2024)

Patients with acute traumatic brain injury (TBI) are at high risk of ventilator-associated pneumonia (VAP), and studies are evaluating preventive strategies. In a **randomized trial of patients with moderate or severe TBI or acute stroke**, those assigned to **ceftriaxone 2 g intravenously (IV) within 12 hours of intubation had lower rates of VAP within seven days** compared with those who received placebo (14 versus 32 percent); treated patients also had a lower 28-day mortality rate (15 versus 25 percent). Adverse effects were similar in both patient groups. Thus, **we now recommend a single dose of ceftriaxone 2 g IV in patients with TBI who require endotracheal intubation to decrease the risk of VAP.**[4]

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