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Article types

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Abstract: less than 300 words. References: up to 30.

REVIEW ARTICLES: Comprehensive, significant, critical, and analytical reviews that include essential information on a well-delineated subject. Reviews must synthesize and critically evaluate available data rather than simply describing the findings.

A general review may be submitted if there is no review on the topic in the literature or if the proposed review will contain ample new and substantive data from published peer-reviewed research studies which will update previous reviews on the topic in the literature and provide a critical analysis leading to new recommendations and conclusions.

When preparing a general review, after the Introduction section, methods used to search the literature (databases including PubMed, search terms, search period, and limits), as well as inclusion and exclusion criteria for articles chosen for the review, should be described. Authors should consider inclusion of studies available on clinicaltrials.gov in the reviews. Study designs and outcomes, including limitations of research included in the review, should be discussed. Authors are encouraged to follow the PRISMA guidelines (Moher D, Liberati A, Tetzlaff J, Altman DG, and the PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses:

The PRISMA Statement. *Ann Intern Med.* 2009; 151:264-269. doi:10.7326/0003-4819-151-4-200908180-00135) for systematic reviews.

Abstract: less than 300 words. References: up to 100.

In addition to general reviews of pharmacotherapy used in specific conditions, the following categories may be considered for focused reviews:

REVIEW ARTICLE - NEW DRUG APPROVAL: Brief reviews of single drug entities that have recently received FDA approval. Manuscripts must include a section comparing existing similar or related FDA-approved medications to clearly describe the role of the new drug in therapy. Authors must ensure that there are ample published peer-reviewed research studies from which to prepare an evidence-based review including recommendations about the place of the new drug relative to other drugs used for the same FDA-approved indication(s) in patients.

Abstract: less than 250 words. References: up to 30; Tables and/or figures: 4

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Abstract: none required; Text: up to 500 words References: up to 10; Tables and/or figures: 2

RESEARCH REPORTS

Background

Brief (2–3 sentences) description of why the study is needed and its importance to the field.

Objective

1. Concise (1–2 sentences) statement of the objective or hypothesis to be addressed.
2. Primary objective identified and stated first, followed by any key secondary objectives.

Methods

1. Design: Clear statement of the study's design, including all aspects (eg. parallel group, randomized, blinded). Indicate if Institutional Review Board or other ethical considerations were needed and/or approved.
2. Participants and setting: The most pertinent inclusion and exclusion criteria, and the setting within which the study was conducted.
3. Interventions: Complete details on treatment (eg. drug dose, route of administration, and duration of administration) and, if pertinent, control interventions.
4. Outcome: Primary and secondary outcome measures, identified as such.

Results

1. Number of participants: Total number, with breakdown into defined groups (eg. treatment, control) shown, followed by number of participants analyzed, again with breakdown into defined groups shown.
2. Outcome: Numbers of participants and events shown, with summary of the outcome in each group reported as effect size (eg. relative risk, odds ratio) and precision (confidence interval). Data on all outcome measures and any negative and/or non-significant findings must be included.
3. Adverse events/safety: Any unintended effects shown; if none, that should be stated.
4. Limitations: Factors affecting accuracy or generalizability of results (eg. small sample size, open-label design).

Conclusion and Relevance

1. Conclusions (not summary) of the study, based only on the results shown, with balance of benefits and harms.
2. What is new about the report and how do these results affect both our knowledge of the medical condition under discussion and future clinical treatment of the disorder? What is the clinical application of the findings, based only on the data obtained (ie. avoid over-generalization)?

Research Report Abstract example:

Background: There is inadequate guidance for clinicians on selection of the optimal dextrose 50% (D50W) dose for hypoglycemia correction in critically ill patients.

Objective: The purpose of this study was to determine the blood glucose (BG) response to D50W in critically ill patients.

Methods: A retrospective analysis was conducted of critically ill patients who received D50W for hypoglycemia (BG < 70 mg/dL) while on an insulin infusion. The primary objective of this study was to determine the BG response to D50W. The relationship between participant characteristics and the dose-adjusted change in BG following D50W was analyzed using simple and multiple linear mixed-effects models.

Results: There were 470 hypoglycemic events (BG < 70 mg/dL) corrected with D50W. The overall median BG response was 4.0 (2.53, 6.08) mg/dL per gram of D50W administered. Administration of D50W per protocol resulted in 32 episodes of hyperglycemia (BG > 150 mg/dL), resulting in a 6.8% rate of overcorrection; 49% of hypoglycemic episodes (230/470) corrected to a BG >100 mg/dL. A multivariable GEE analysis showed a significantly higher BG response in participants with diabetes (0.002) but a lower response in those with recurrent hypoglycemia (P=0.049). The response to D50W increased with increasing insulin infusion rate (P = 0.022). Burn patients experienced a significantly larger BG response compared with cardiac, medical, neurosurgical, or surgical patients.

Conclusion and Relevance: This represents the first report of the BG response to D50W in critically ill patients and the observed median effect of D50W on BG was approximately 4 mg/dL per gram of D50W administered. Application of these data may aid in rescue protocol development that may reduce glucose variability associated with hypoglycemic episodes and the correction.

REVIEW ARTICLES

Objective

Explain the rationale and goals for the review.

Data Sources Provide specific search details in the abstract and specify the resources employed in the search and include date ranges, search terms, and limits.

Study Selection and Data Extraction

Quantify the original reports included and how they were chosen, as well as the methods used for abstracting the data.

Data Synthesis

Summarize main results and provide interpretation of the data from various studies.

Relevance to Patient Care and Clinical Practice (for general reviews)

What is new about the review article and how do the evaluated findings affect both our knowledge of the medical condition under discussion and future clinical treatment of the disorder?

Relevance to Patient Care and Clinical Practice in Comparison to Existing Drugs (for New Drug Approval reviews)

In addition, addressing the questions raised for the general reviews above, New Drug Approval manuscripts should also include the merits of the new drug under discussion relative to those existing drug therapies.

Conclusions

Summarize the key “take-home” points from the review. NOTE: Reviews that can only conclude with the suggestion that “additional studies are needed” will be of a lower priority than reviews that can provide direct clinical recommendations or assessments as based on the literature being reviewed.

Review Article Abstract example:

Objective: To describe properties of cobicistat and ritonavir; compare boosting data with atazanavir, darunavir, and elvitegravir; and summarize antiretroviral and comedication interaction studies, with a focus on similarities and differences between ritonavir and cobicistat. Considerations when switching from one booster to another are discussed.

Data Sources: A literature search of MEDLINE was performed (1985 to April 2017) using the following search terms: cobicistat, ritonavir, pharmacokinetic, drug interactions, booster, pharmacokinetic enhancer, HIV, antiretrovirals. Abstracts from conferences, article bibliographies, and product monographs were reviewed.

Study Selection and Data Extraction: Relevant English-language studies or those conducted in humans were considered.

Data Synthesis: Similar exposures of elvitegravir, darunavir, and atazanavir are achieved when combined with cobicistat or ritonavir. Cobicistat may not be as potent a CYP3A4 inhibitor as ritonavir in the presence of a concomitant inducer. Ritonavir induces CYP1A2, 2B6, 2C9, 2C19, and uridine 5'-diphospho-glucuronosyltransferase,

whereas cobicistat does not. Therefore, recommendations for cobicistat with comedications that are extrapolated from studies using ritonavir may not be valid. Pharmacokinetic properties of the boosted antiretroviral can also affect interaction outcome with comedications. Problems can arise when switching patients from ritonavir to cobicistat regimens, particularly with medications that have a narrow therapeutic index such as warfarin.

Relevance to Patient Care and Clinical Practice: This review compares and contrast the pharmacological, pharmacokinetics, and drug interaction studies for ritonavir and cobicistat and a discussion on considerations when switching from one booster to another is included to guide clinicians.

Conclusions: When assessing and managing potential interactions with ritonavir- or cobicistat-based regimens, clinicians need to be aware of important differences and distinctions between these agents. This is especially important for patients with multiple comorbidities and concomitant medications. Additional monitoring or medication dose adjustments may be needed when switching from one booster to another.

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For review articles, a new subsection in the text just prior to the “Summary” section should be added and titled “Relevance to Patient Care and Clinical Practice” and similarly contain information in more detail as outlined on page 5 of these author guidelines for the abstract section of this heading.

For New Drug Approval reviews, the penultimate section of the main text should be titled “Relevance to Patient Care and Clinical Practice in Comparison to Existing Drugs”, and also include the merits of the new drug under discussion relative to that of existing drug therapies.

Abbreviations must be defined upon first use in the text. Use of abbreviations should be limited to, for example, lengthy terms; the majority of drug names should not be abbreviated. USANs or, when appropriate, chemical names, must be used for all drugs. Manufacturers’ code numbers should be used only when a generic name is not yet available. Trade names should be included only in the text (and not in the title) to distinguish between different trade preparations, for some combination drugs, or in reviews of drugs that have been recently approved by the FDA.

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Article

Basaran O, Filiz Basaran N, Cekic EG, et al. Prescription patterns of oral anticoagulants in nonvalvular atrial fibrillation (PROPER study). *Clin Appl Thromb Hemost* 2017;23:384- 391. doi:10.1177/1076029615614395

Article with URL

National Association of Community Health Centers. Community health center chartbook <http://www.nache.org/wpcontent/uploads/2017/06/Chartbook2017.pdf>. Accessed August 30, 2017.

Abstract

Tringale KR, Shi Y, Hattangadi JA. Marijuana utilization in cancer patients: a comprehensive analysis of national health and nutrition examination survey data from 2005-2014 [abstract]. *Int J Radiat Oncol* 2017;99:S11. doi:10.1016/j.ijrobp.2017.06.042

Journal Supplement

Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. *Endocr Pract* 2017;23(suppl 2):1-87. doi:10.4158/EP171764. APPGL.

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Jardiance (empagliflozin) [package insert]. Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, January 2020.

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