



AbstractFull TextSupplementsRelated Reports

Wijkman, 2022

**Effects of sacubitril/valsartan on glycemia in patients with diabetes and heart failure: the PARAGON-HF and PARADIGM-HF trials.**  
BACKGROUND Compared with enalapril, sacubitril/valsartan lowered HbA1c and reduced new insulin therapy in patients with heart failure with reduced ejection fraction (HFrEF) and diabetes in the PARADIGM-HF trial. We sought to assess the glycemic effects of sacubitril/valsartan in heart failure with preserved ejection fraction (HFpEF) and diabetes, and across the spectrum of left ventricular ejection fraction (LVEF) in heart failure and diabetes. METHODS We compared the effect of sacubitril/valsartan, relative to valsartan, on HbA1c, new insulin therapy and hypoglycemia in the randomized controlled trial PARAGON-HF, and performed pooled analyses of PARAGON-HF and PARADIGM-HF. RESULTS Among 2395 patients with HFpEF and diabetes in PARAGON-HF, sacubitril/valsartan compared with valsartan reduced HbA1c (baseline-adjusted between-group difference in HbA1c change at 48 weeks: - 0.24%, 95% CI - 0.33 to - 0.16%, P < 0.001). Numerically, new insulin treatment was initiated less often in the sacubitril/valsartan group than in the valsartan group, but the difference was not statistically significant (12.8% vs. 16.1%; HR: 0.80, 95% CI 0.62-1.02, P = 0.07). Hypoglycemia adverse event reports were low, but more frequent in those receiving sacubitril/valsartan than in the valsartan group (4.2% vs. 2.6%; HR: 1.64, 95% CI 1.05-2.56, P = 0.030). In a pooled analysis of PARAGON-HF and PARADIGM-HF, the effect of sacubitril/valsartan on change in HbA1c was not significantly modified by LVEF (Pinteraction = 0.56). Across the spectrum of LVEF, sacubitril/valsartan reduced new insulin therapy (HR: 0.75, 95% CI 0.63-0.89, P = 0.001), compared with enalapril or valsartan. CONCLUSIONS Sacubitril/valsartan reduced HbA1c and new insulin therapy in patients with heart failure and diabetes across the spectrum of LVEF but may be associated with a slightly higher risk for hypoglycemia. Trial registration ClinicalTrials.gov NCT01920711.

Population/ProblemInterventionOutcome

KeywordsBibliographic fields

Edit

Navigation

BackSkip

Screening

Full Text ReviewP(Inclusion): 0.00

Full Text Uploaded!

Exclude:

Search Reasons

Select Reason

Systematic Review/Metanalysis

Does not report patients with heart failure with redu...

secondary analysis

Retrospective study

Does not report therapies of interest

Sub-analysis of RCT

Potential bias in patient population

Include:

Include

Tagging

Comments (0)

History

Your task in screening should be to identify, based on the Abstract content, whether the record falls **BACKGROUND** under any Exclusion Reason, or whether it is on-topic for your review and satisfies your criteria for inclusion.

The Screening page displays an abstract highlighted with **RoboPICO**, which is an open source fork of the models offered in **RobotReviewer** that identifies the Population, Interventions, and Outcomes in an abstract. Then, see on the right a panel to select Exclusion Reasons or Include the article in question.

Using the scite banner

Above your abstract, you can see the scite banner, which displays the number of times the publication in question was cited, supported, mentioned, and contrasted. If you click the banner, you can see more citation-related information provided by scite.ai, including retractions!

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Include:

Include

Tagging

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3. Decide if study should be Included or Excluded

If the abstract does not provide enough information for you to decide if it should be Included or

Excluded, click on the study source button (in this case PubMed, see red arrow below) and source the full text of the study.



If you read the FULL TEXT and decide it should be included, check the “Full Text Review” box.

## Exclude Records

If you read the abstract and find that one or more of your Exclusion Reasons (red box above) are applicable, click on the reason that applies to that specific study. This will apply your reason and automatically bring up the next study to be screened.

## Include Records

If you read the abstract and find that none of your Exclusion Reasons apply, and that (based on information available to you) the publication in question is relevant to your review, select “Include” (see red box above).

## Skipping a study

Having a hard time deciding whether to include or exclude a study? You can hit skip and leave it unscreened until you're ready to make a decision.

The screenshot displays the Wikiman 2022 interface. The main content area shows an abstract titled "Effects of sacubitril/valsartan on glycemia in patients with diabetes and heart failure: the PARAGON-HF and PARADIGM-HF trials." The abstract text discusses the background, methods, results, and conclusions of the study. The sidebar on the right contains a "Navigation" section with a "Skip" button highlighted in red. Below this is a "Screening" section with a "Full Text Review" checkbox, a "Full Text Uploaded!" button, and a "Select Reason" dropdown menu. The "Select Reason" dropdown is open, showing a list of reasons for exclusion, including "Systematic Review/Metanalysis", "Does not report patients with heart failure with reduced...", "secondary analysis", "Retrospective study", "Does not report therapies of interest", "Sub-analysis of RCT", and "Potential bias in patient population". The "Include:" button is highlighted in blue.

## Add Exclusion Reasons on the Fly

You can add Exclusions Reasons as you screen without leaving the Screening page. To do so, in the Screening module, open the Exclusion Reason drop-down and begin typing in an Exclusion Reason.

If the reason of interest has not yet been configured, you will be presented with the ability to "Add Option." Select this option, and write out your full Exclusion Reason. Once you have added it, it will be added to the Exclusion Reason drop-down and the Configure Exclusion Reasons page, and will be automatically applied to the study you are currently screening. To confirm that the new reason should be applied, select "Exclude".

## Unscreening a study

If you have included or excluded a study that you want to revert to 'unscreened' status so that it can be reviewed again, you can unscreen it by finding the study of interest in [Study Inspector](#), and then selecting the icon next to the Include button on the study you want to unscreen. A pop-up will appear and you can then click "Unscreen" to unscreen that single study.

The screenshot displays the Wikiman 2022 interface. The main content area shows an abstract titled "Design and rationale for a comparison study of Olmesartan and Valsartan On myocardial metabolism In patients with Dilated cardiomyopathy (OVOID) trial: study protocol for a randomized controlled trial." The abstract text discusses the background, methods, and discussion of the study. The sidebar on the right contains a "Screening" section with a "Full Text Review" checkbox, a "Full Text Uploaded!" button, and a "Select Reason" dropdown menu. The "Select Reason" dropdown is open, showing a list of reasons for exclusion, including "Systematic Review/Metanalysis", "Does not report patients with heart failure with reduced...", "secondary analysis", "Retrospective study", "Does not report therapies of interest", "Sub-analysis of RCT", and "Potential bias in patient population". The "Include:" button is highlighted in blue, and a red box highlights the "Add" button next to it.

Note: if you want to unscreen multiple studies, you can also do so using [Bulk Actions](#)!

## 4. Upload the Full Text

In general, uploading a Full Text should be completed only for Included records, and doing so assists in preparing the Tagging step.

For instructions on how to upload a Full Text PDF, click [here](#).

### No Full Text

If you cannot source a full text for the study in question, you can use the “No Full Text” option to designate an Exclusion Reason specifically to address those records.

For those records, first configure an Exclusion Reason as “No Full Text” in the Configure Exclusion Reasons page:

Add

Exclusion Reasons

Import Set

Reason		Excluded Records	No Full Text	
pediatrics		3	Signals No FT <input type="checkbox"/>	
Not Published in English		2	Signals No FT <input type="checkbox"/>	
Valsartan Heart Failure Trial		2	Signals No FT <input type="checkbox"/>	
Correspondence		1	Signals No FT <input type="checkbox"/>	
Based on retracted study		1	Signals No FT <input type="checkbox"/>	
ST-Segment Elevation Myocardial Infarction		1	Signals No FT <input type="checkbox"/>	
Reports patients with ejection fraction above 45 ...		1	Signals No FT <input type="checkbox"/>	
Not a pharmacological treatment		1	Signals No FT <input type="checkbox"/>	
No Ivabradine		1	Signals No FT <input type="checkbox"/>	
No full text		0	Signals No FT <input checked="" type="checkbox"/>	

Then, apply this Exclusion Reason to all records where a full text was sought but not found.

**Implications:** Marking “No Full Text” is a special PRISMA category, so the specific reason you configure for this purpose will be given its own listing in your [PRISMA chart](#).

## 5. Continue Screening

Once you have clicked “Include” or “Exclude” (or “skip”) for any study, you should be automatically shown the next study.

If you are screening from [Inspector](#), you can use the arrows in the far left and right of the screen to navigate up or down, respectively, or click out to view the Inspector study list.

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Last update: **2022/11/20 01:11**