

# Carotid artery revascularization:

A systematic review and meta-analysis comparing clinical outcomes of second vs. first generations stents

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on behalf of [CARMEN](#) Collaborators

[C](#)arotid [R](#)evascularization systematic review and [M](#)eta-[a](#)[N](#)alysis

# Disclosure

Speaker name:

Adam Mazurek MD, PhD

I have the following potential conflicts of interest to report:

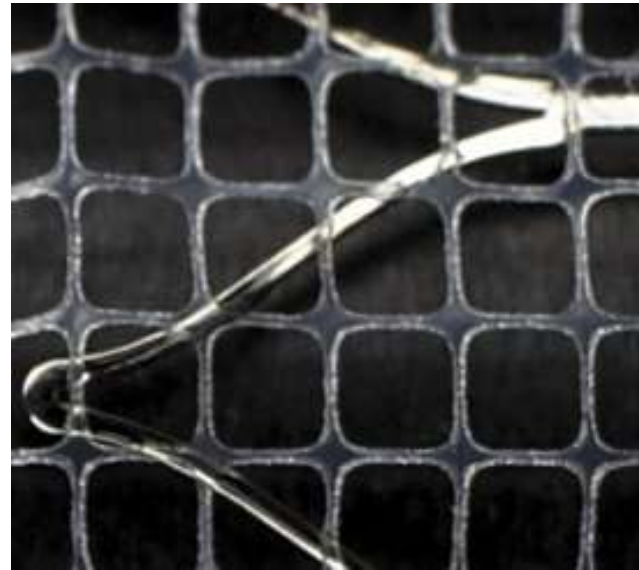
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
  
- I do not have any potential conflict of interest

# Introduction

- Comparisons of data in individual studies suggest that the use of **second-generation carotid stents (SGS; dual-layer, mesh-covered)** may improve clinical outcomes.



Casper/RoadSaver



Gore Carotid Stent



CGuard MicroNET Stent

- This has not been systematically evaluated.

# Purpose

1. Are the 30-day and 12-month outcomes for **SGS** *different* than those for first-generation stents (FGS) ?
2. Is there a '*class effect*' for SGS ?

**FGS** – first generation stents  
**SGS** – second generation stents  
(mesh/dual-layer)

# METHODS

**We performed a systematic review and meta-analysis (PRISMA\* methodology) of clinical studies that have used First-generation carotid stents (FGS; open or close-cell) and Second-generation carotid stents (SGS).**

1. Evaluation of typically reported 30-day and 12-month endpoints.
3. PubMed search ('carotid' + 'stent' + 'trial' or 'study').
4. Prespecified criteria for record initial screening (CADIMA#).
5. Prespecified criteria for study eligibility.
6. Cumulative data integration.
7. Random effect model meta-analysis.
8. Endpoints compared for **FGS** (open/close-cell) vs **SGS** (as a group and per individual stent types – **RoadSaver/Casper Stent, Gore Stent, CGuard MicroNET Stent**)

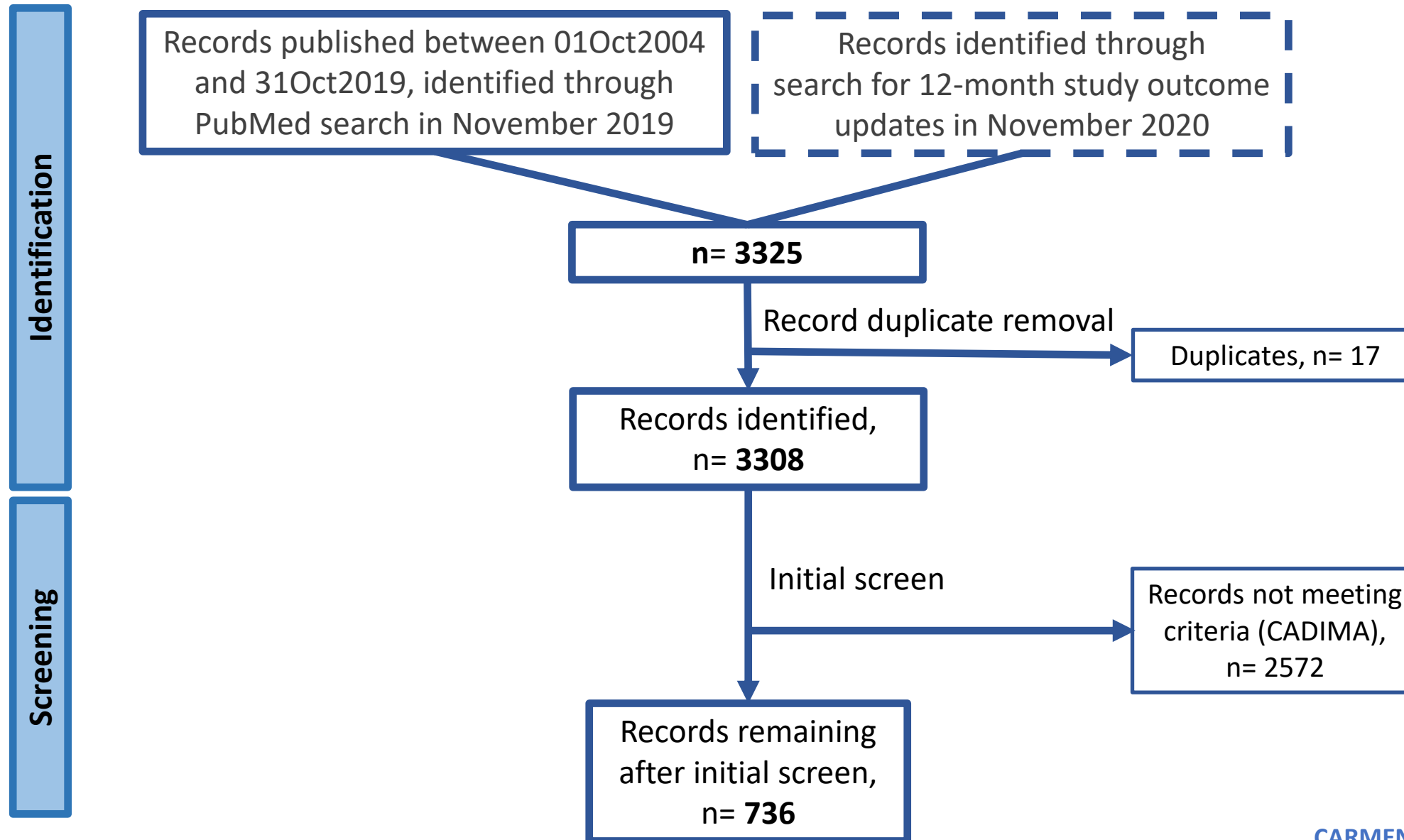
\*Moher D *et al.* Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *BMJ*. 2009

# [www.cadima.info](http://www.cadima.info)

# Carotid revascularization outcomes of interest

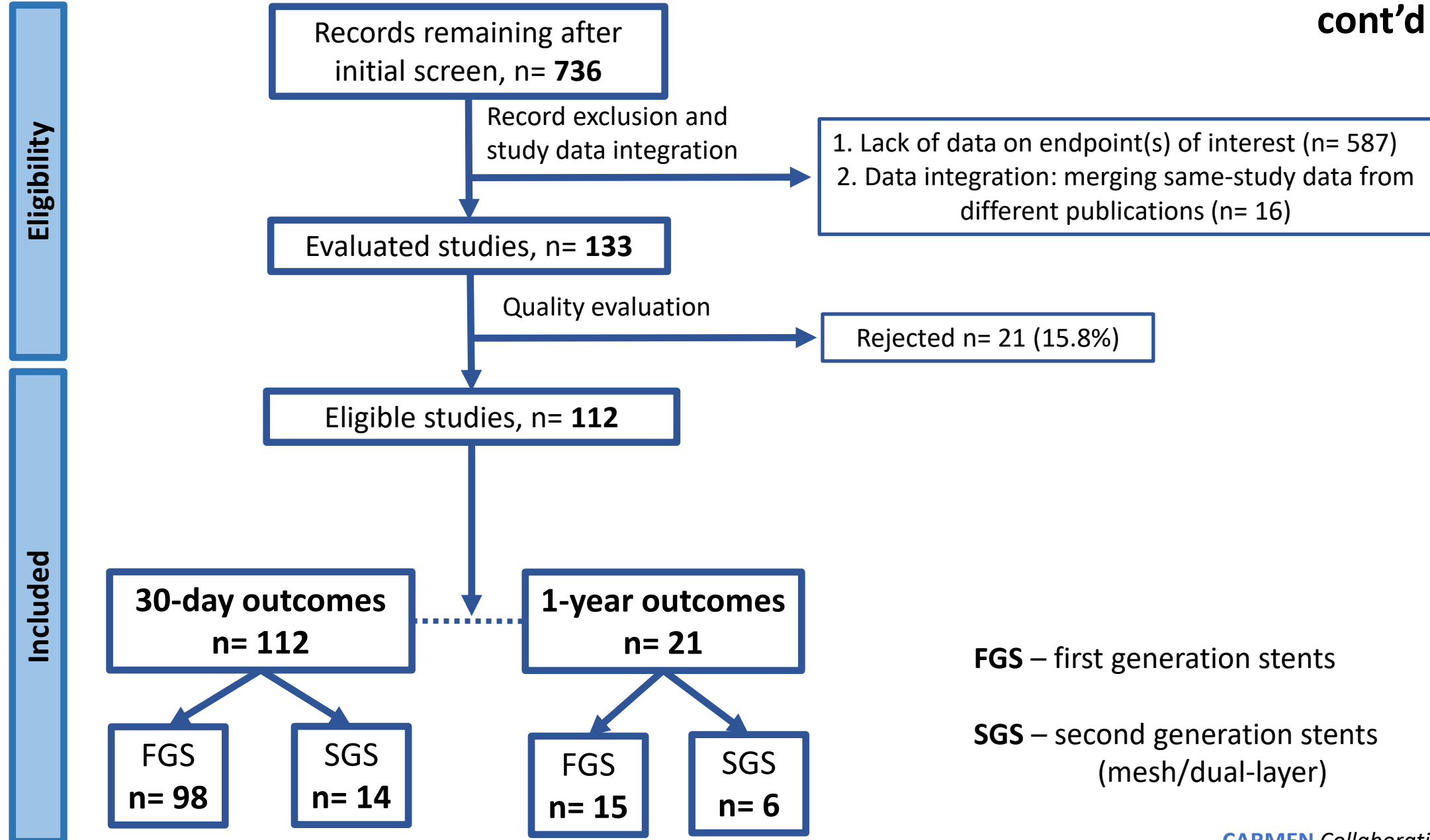
- Random search for typical 30-day outcomes and 12-month outcomes in carotid revascularization studies (2004-2019)
- Identification of:                   50 studies with 30-day outcomes  
  50 studies with 12-month outcomes
- *Typically-reported 30-day outcomes:* **DEATH (D)**  
**(any) STROKE (S)**  
**MYOCARDIAL INFARCTION (MI)**
- *Typically-reported 12-mo outcomes:* **ipsilateral STROKE (IS)**  
**RESTENOSIS (R/ISR)**

# CARMEN Systematic review and meta-analysis flowchart (PRISMA)



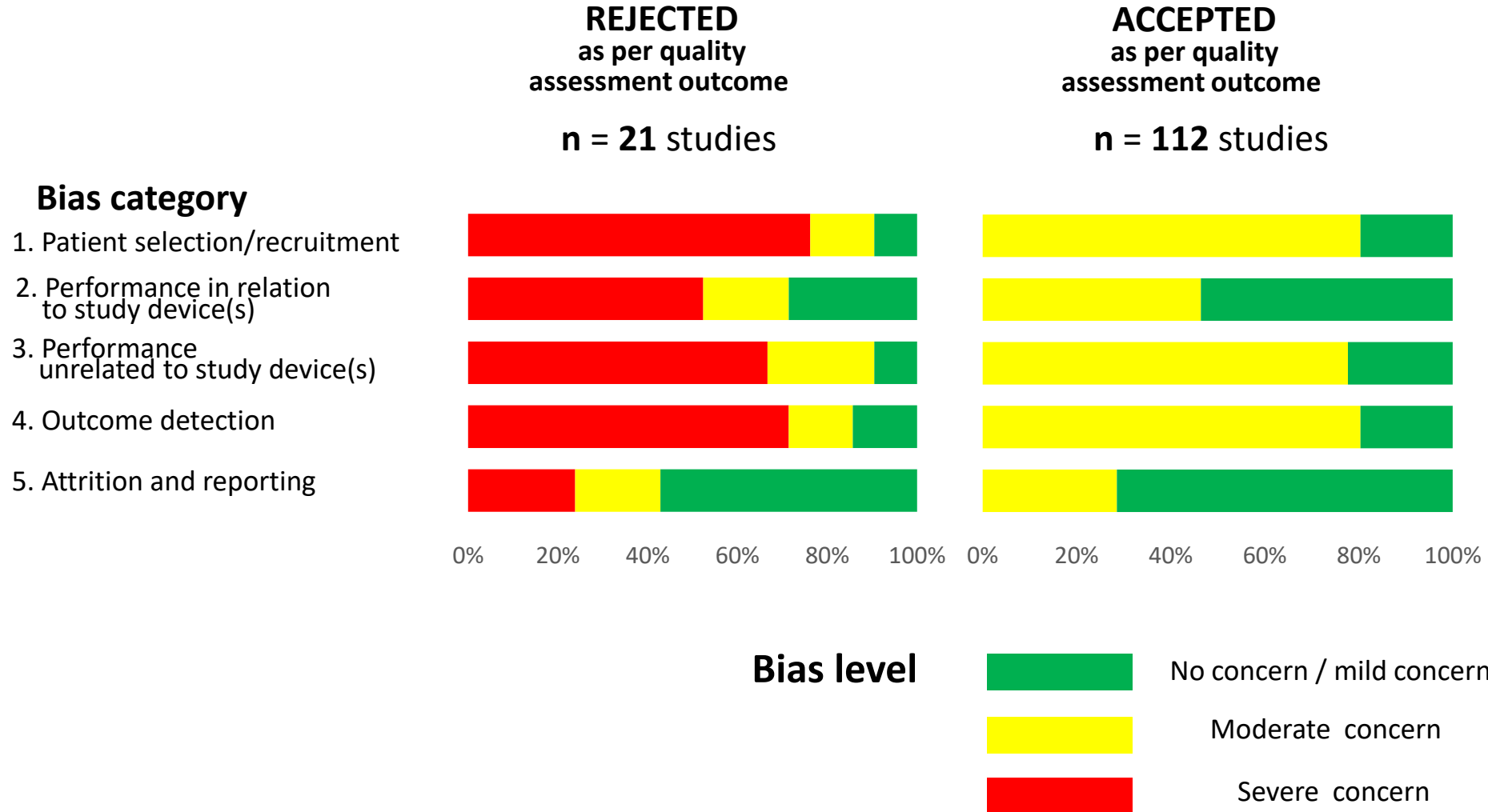
# CARMEN Systematic review and meta-analysis flowchart (PRISMA)

cont'd





# Data Quality: Study Bias Systematic Assessment



Severe bias (red) was reason for rejection.

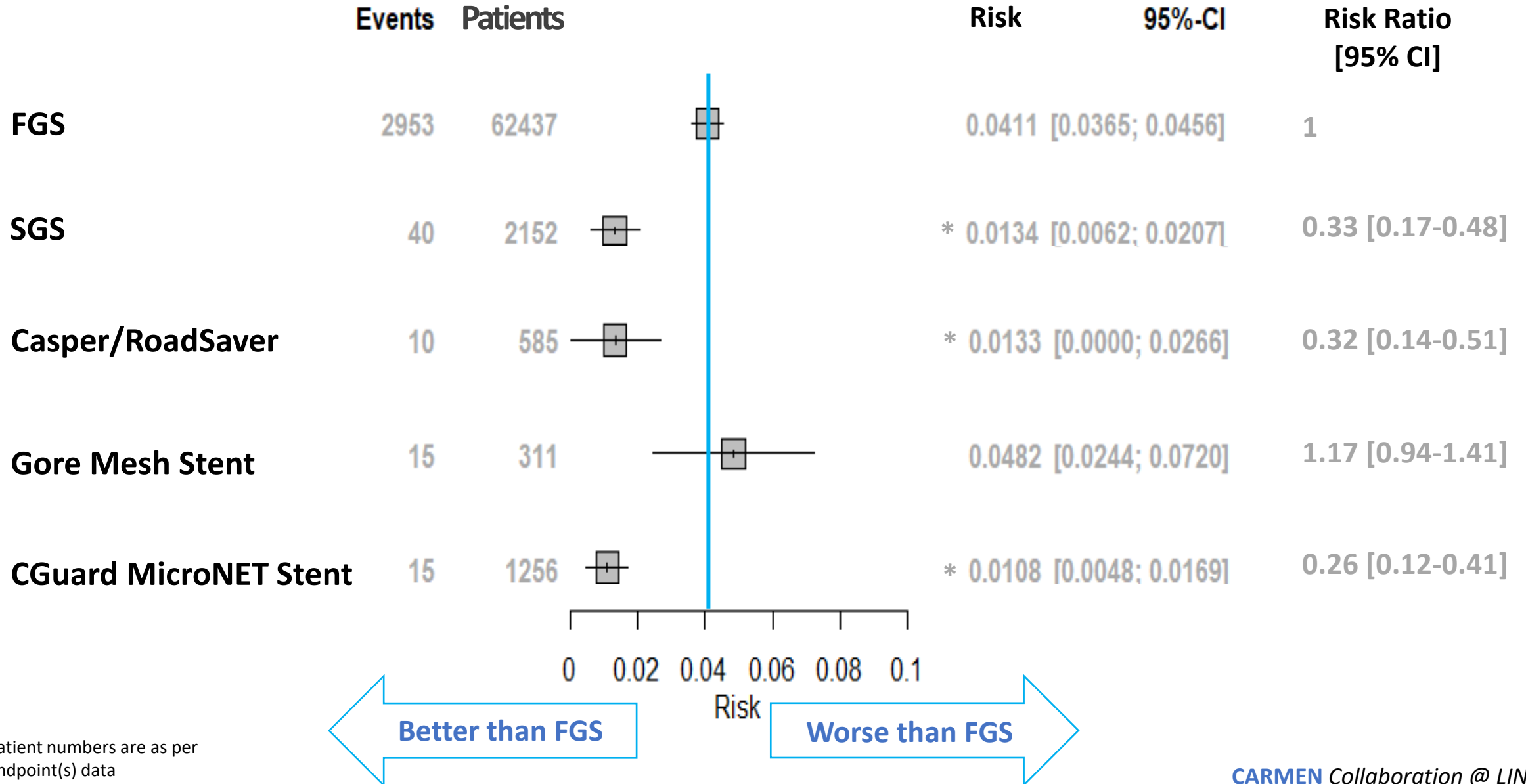
# Stent type comparisons: Pooled populations characteristics

	<b>FGS</b>	<b>SGS</b>	p	Open-cell FGS	Close-cell FGS	p open vs close	p open vs SGS	p close vs SGS
No of studies	98	14	-	29	12	-	-	-
No of patients	65,891*	2,152*	-	20,676*	7,598*	-	-	-
Age [mean] ± SD	70.1 (2.8)	71.9 (2.5)	0.02	70.4 (3.2)	69.3 (3.4)	0.60	0.32	0.13
Male [%]	68%	73%	0.046	68%	66%	0.92	0.12	0.15
Symptomatic [%]	45%	41%	0.40	43%	50%	0.61	0.94	0.45
Diabetic [%]	34%	32%	0.43	35%	36%	0.71	0.88	0.61
CAD [%]	51%	47%	0.55	48%	55%	0.59	0.98	0.98
AF [%]	6%	3%	0.37	3%	ND	-	0.99	-
Contralateral occlusion [%]	10%	16%	0.22	10%	12%	0.87	0.63	0.99

**FGS** – first generation stents; **SGS** – second generation stents (mesh/dual-layer)

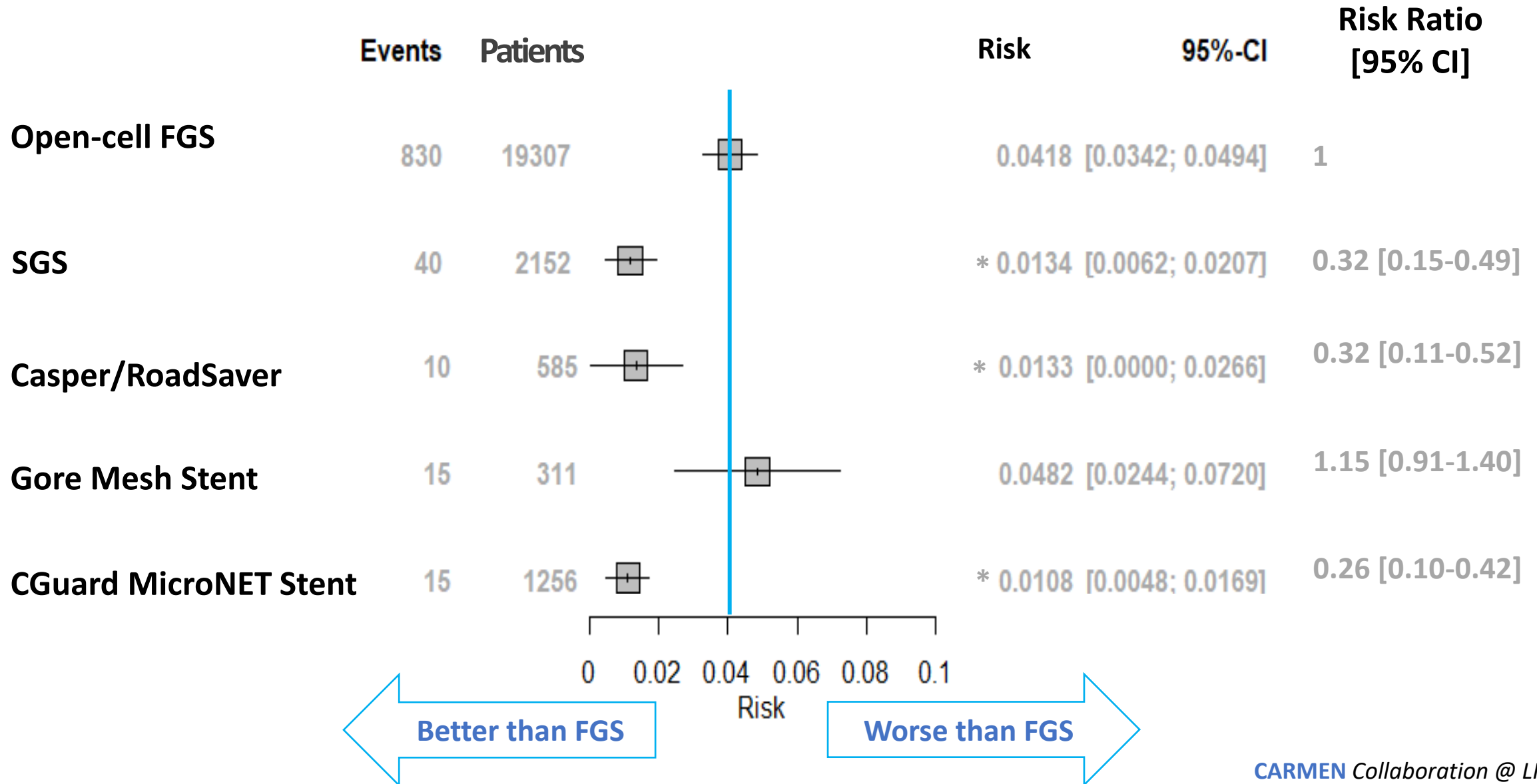
\*Data per total number of patients as per published patient characteristics

# 30-day Death/Stroke/MI: FGS vs SGS

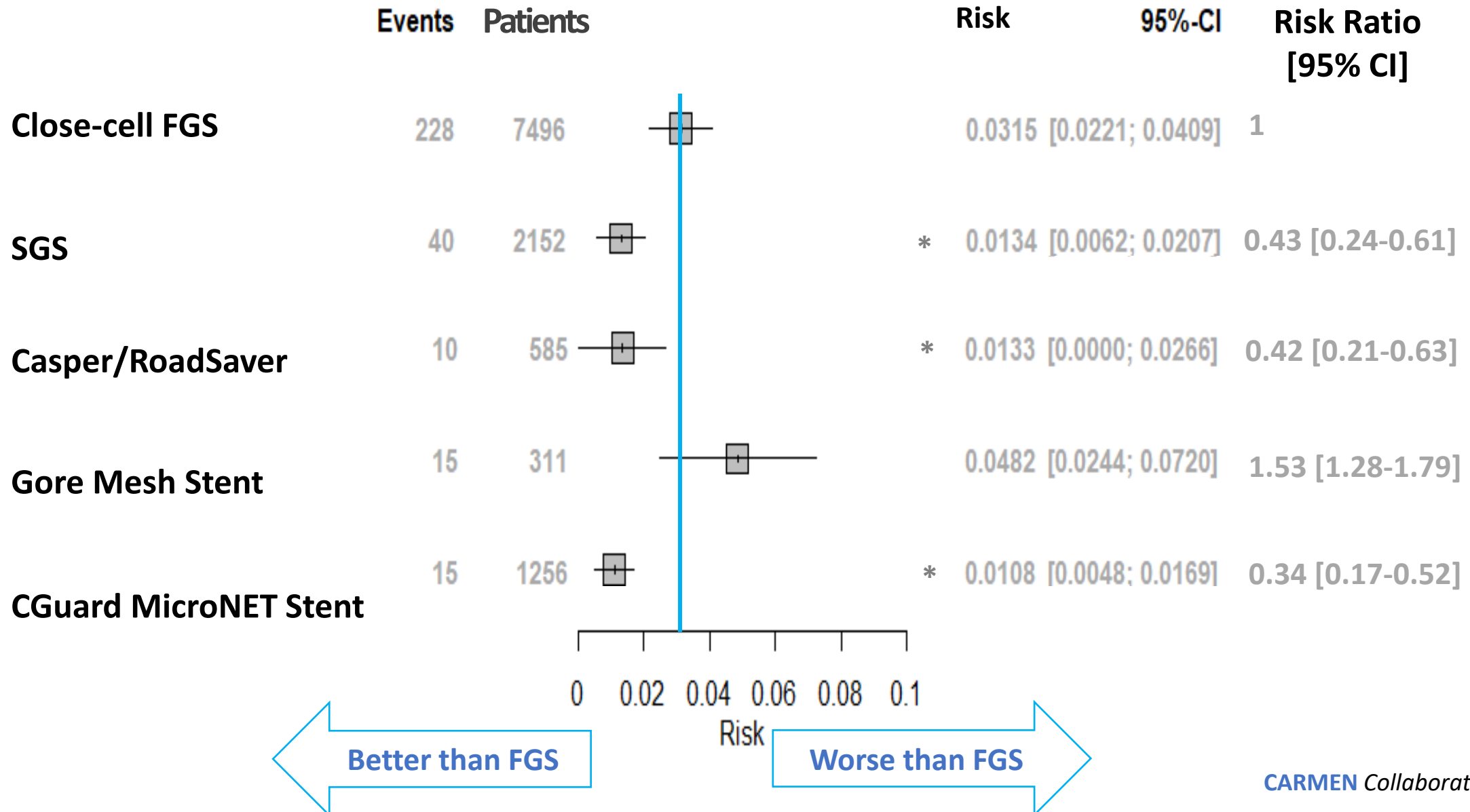


Patient numbers are as per endpoint(s) data

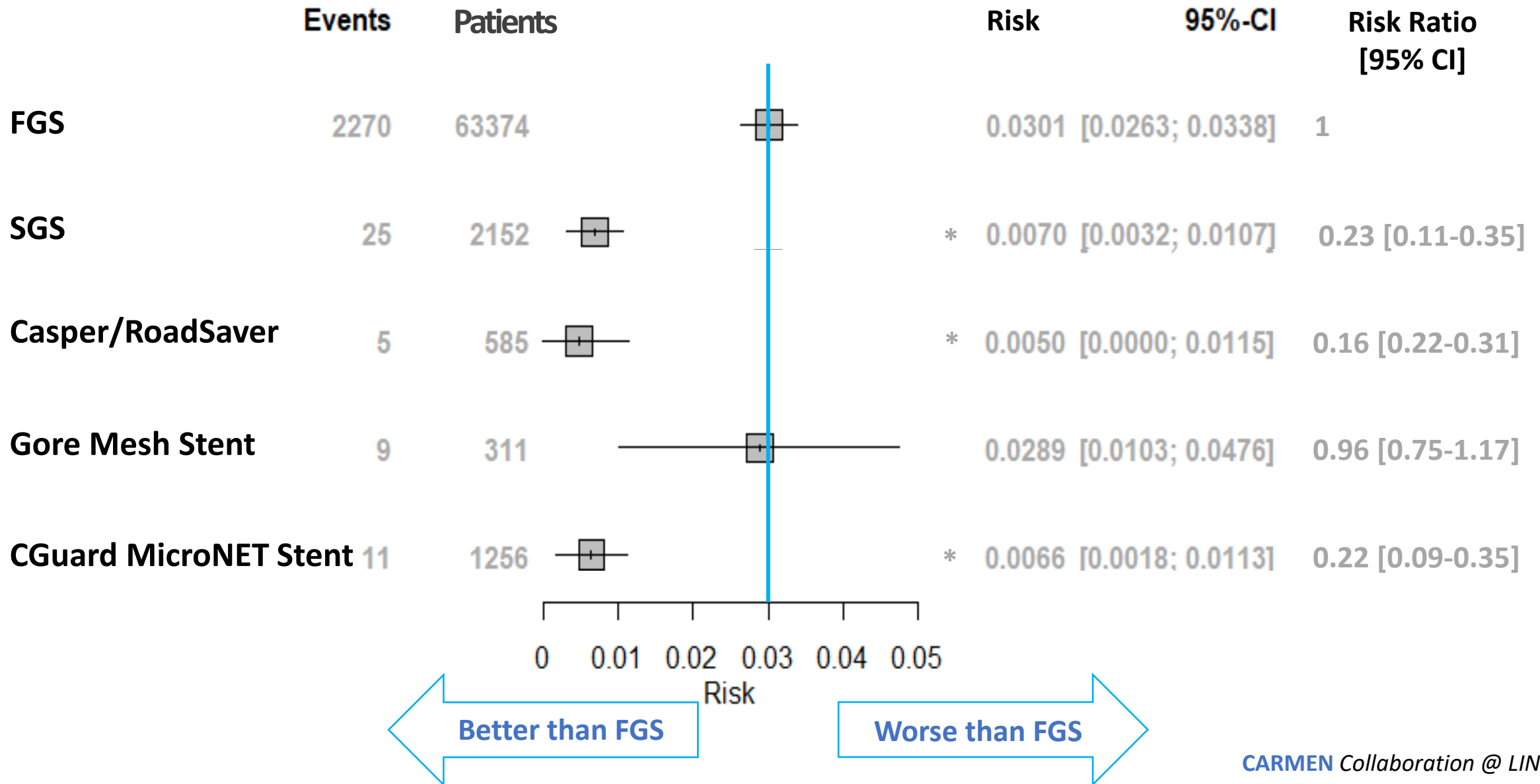
# 30-day Death/Stroke/MI: open-cell FGS vs SGS



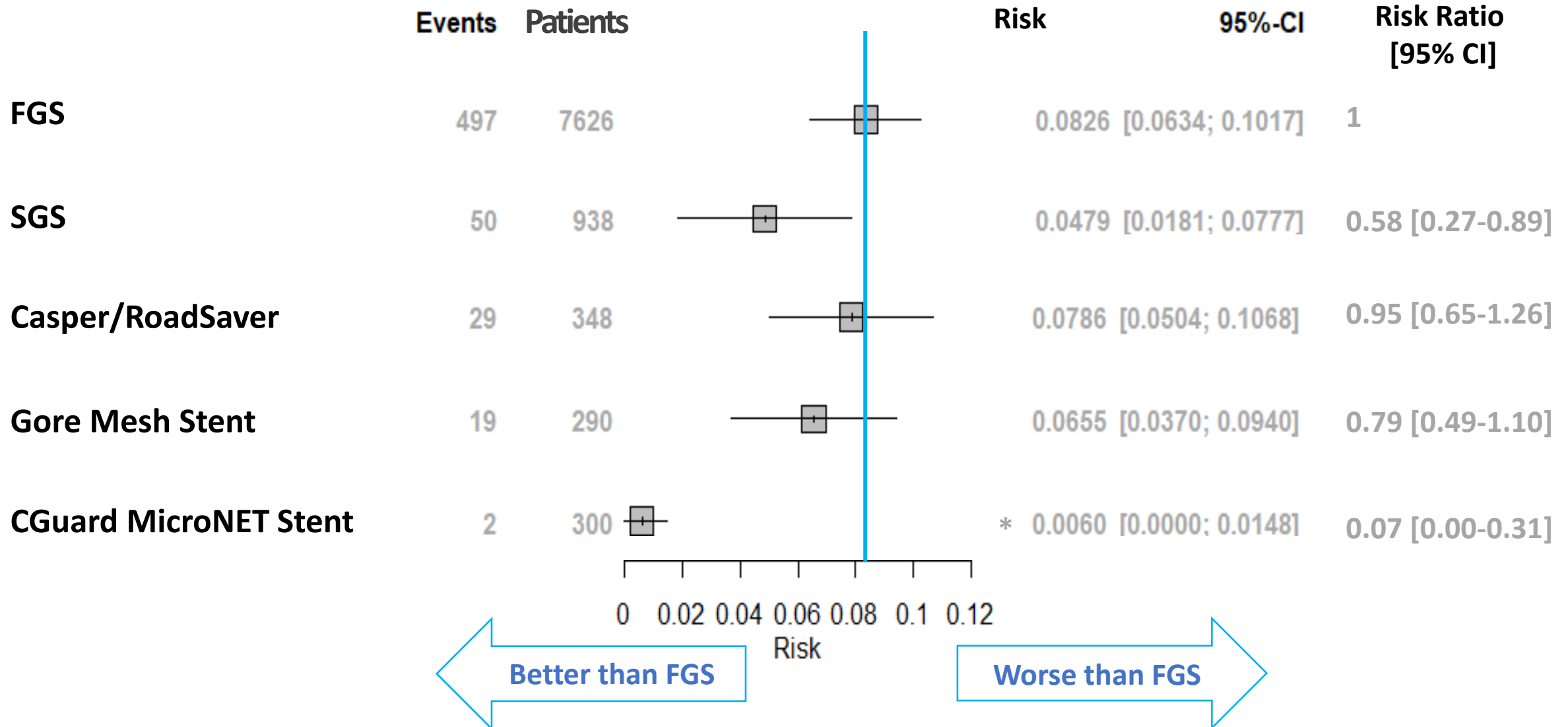
# 30-day Death/Stroke/MI: close-cell FGS vs SGS



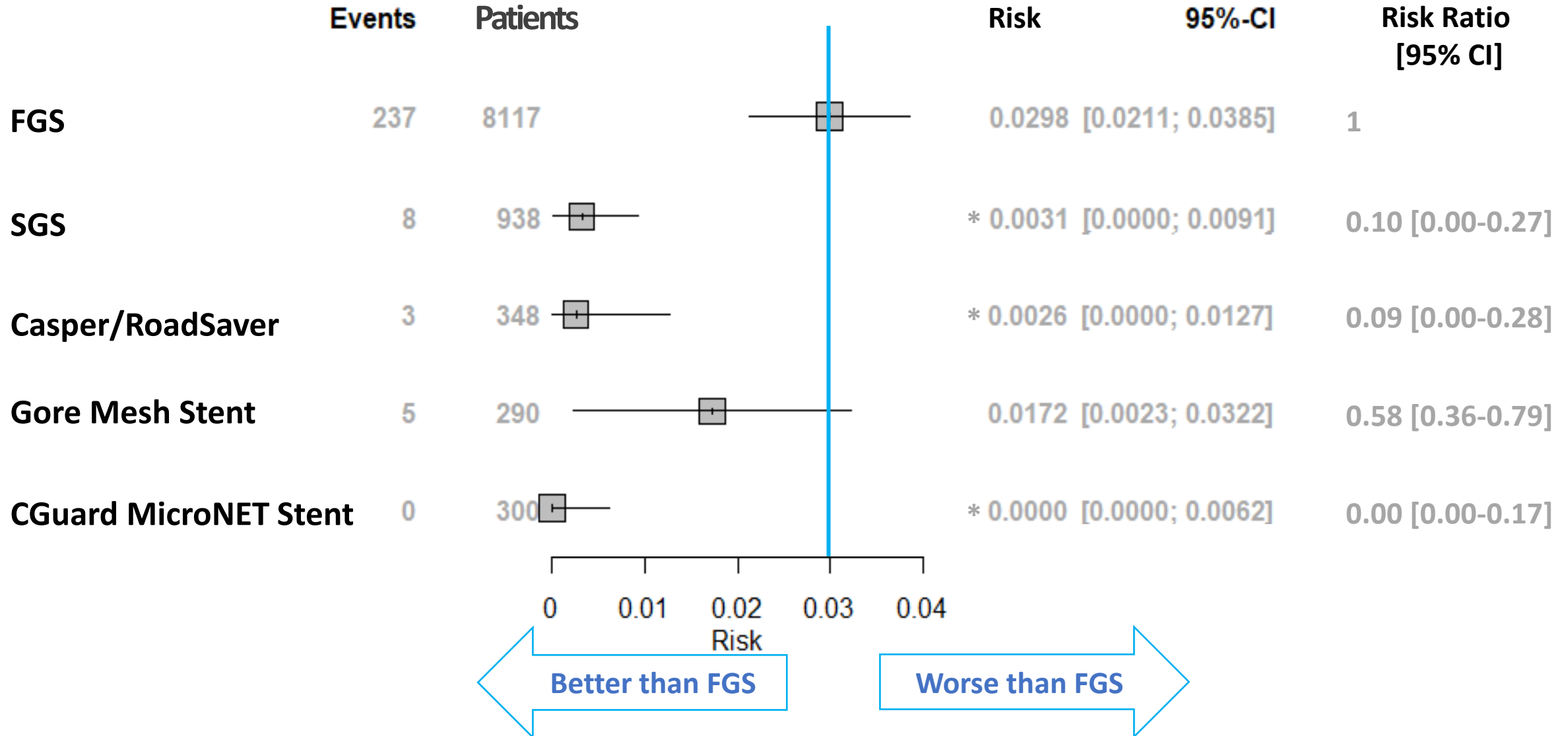
# 30-day Stroke: FGS vs SGS



# 12-month Ipsilateral Stroke/ISR: FGS vs SGS

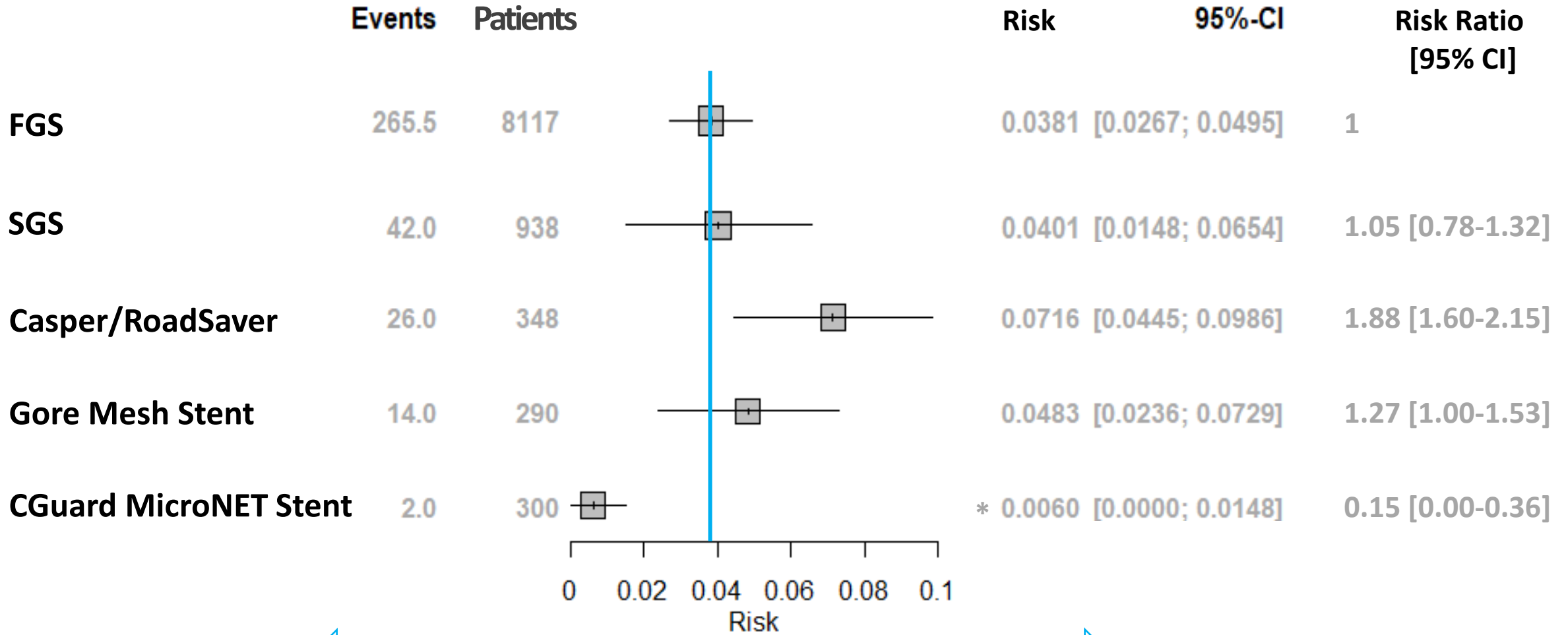


# 12-month Ipsilateral Stroke: FGS vs SGS





# 12-month ISR: FGS vs SGS



← Better than FGS

→ Worse than FGS

# SGS vs CEA

**SGS** – second generation stents  
(mesh/dual-layer)

# Purpose

- Is there a difference in **30-day**  
**12-month** outcomes

for SGS vs **CEA** ?

# CEA vs SGS meta-analysis

Major  
RCTs  
Involving CEA

## 1. **CEA** pooled data

**SAPPHIRE**  
**EVA 3S**  
**SPACE-1**  
**ICSS**  
**CREST**  
**ACST-1**  
**ACT-1**  
**Manhaim**  
**SPACE-2**

CEA in  
Contemporary  
Clinical Practice

## 2. **CEA** in Vascular Quality Initiative (**VQI**) database\*

\* Dakour-Aridi H, et al. *Ann Vasc Surg.* 2020;65:1-9  
Columbo JA, et al. *J Vasc Surg.* 2019;69:104-109

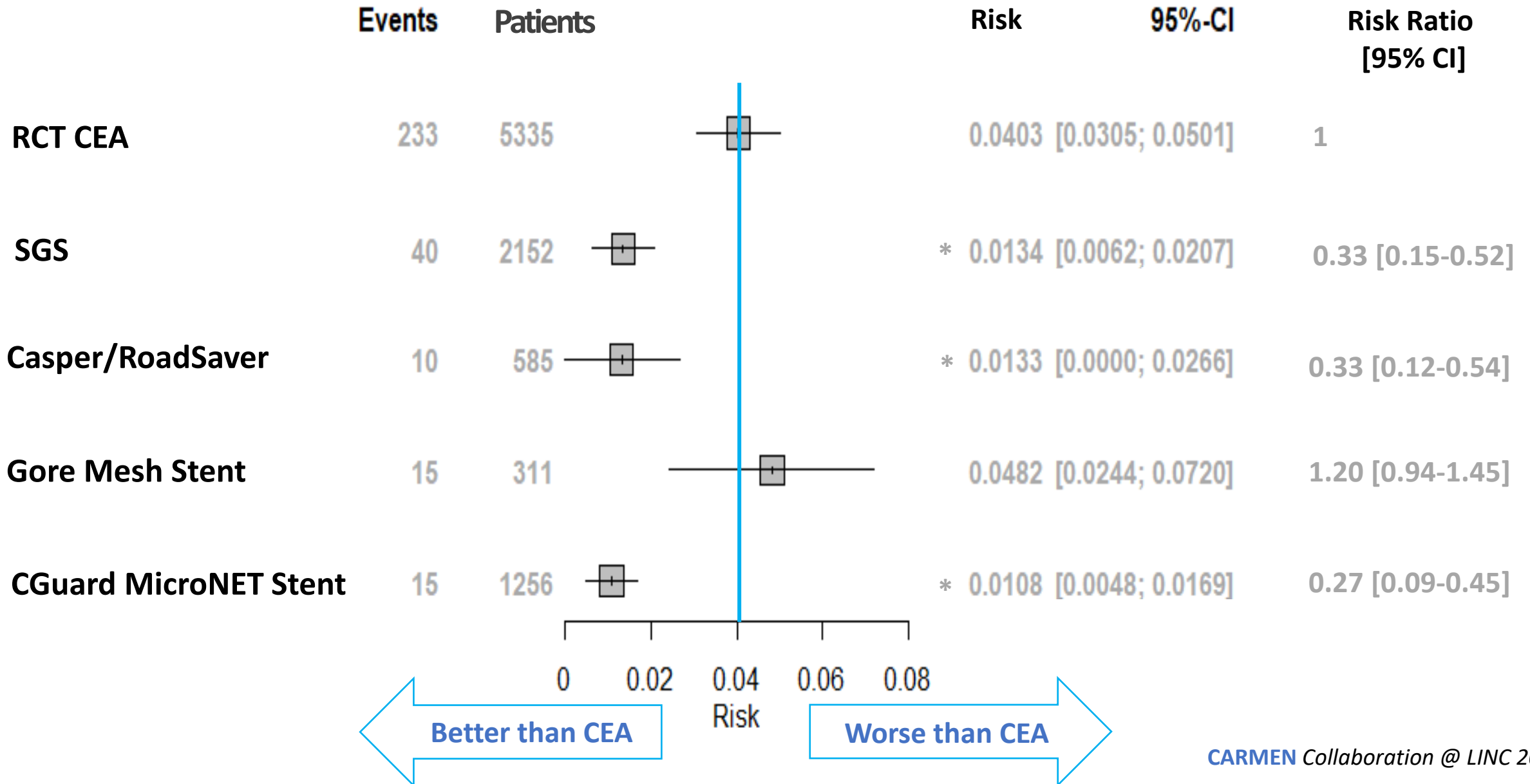
# CEA vs SGS: Populations Characteristics

	RCTs CEA	VQI CEA	SGS	p RCTs-CEA vs SGS	p VQI-CEA vs SGS
No of studies	9	2	14	-	-
No of patients	5,335*	95,776*	2,152*	-	-
Age [mean] ± SD	69.4 (1.5)	71	71.9 (2.5)	0.03	-
Male [%]	69%	61%	73%	0.71	0.29
Symptomatic [%]	37%	23%	41%	0.75	0.83
Diabetic [%]	29%	35%	32%	0.44	0.99
CAD [%]	41%	27%	47%	0.75	0.35
AF [%]	3%	nd	3%	1.0	-
Contralateral occlusion [%]	7%	nd	16%	0.56	-

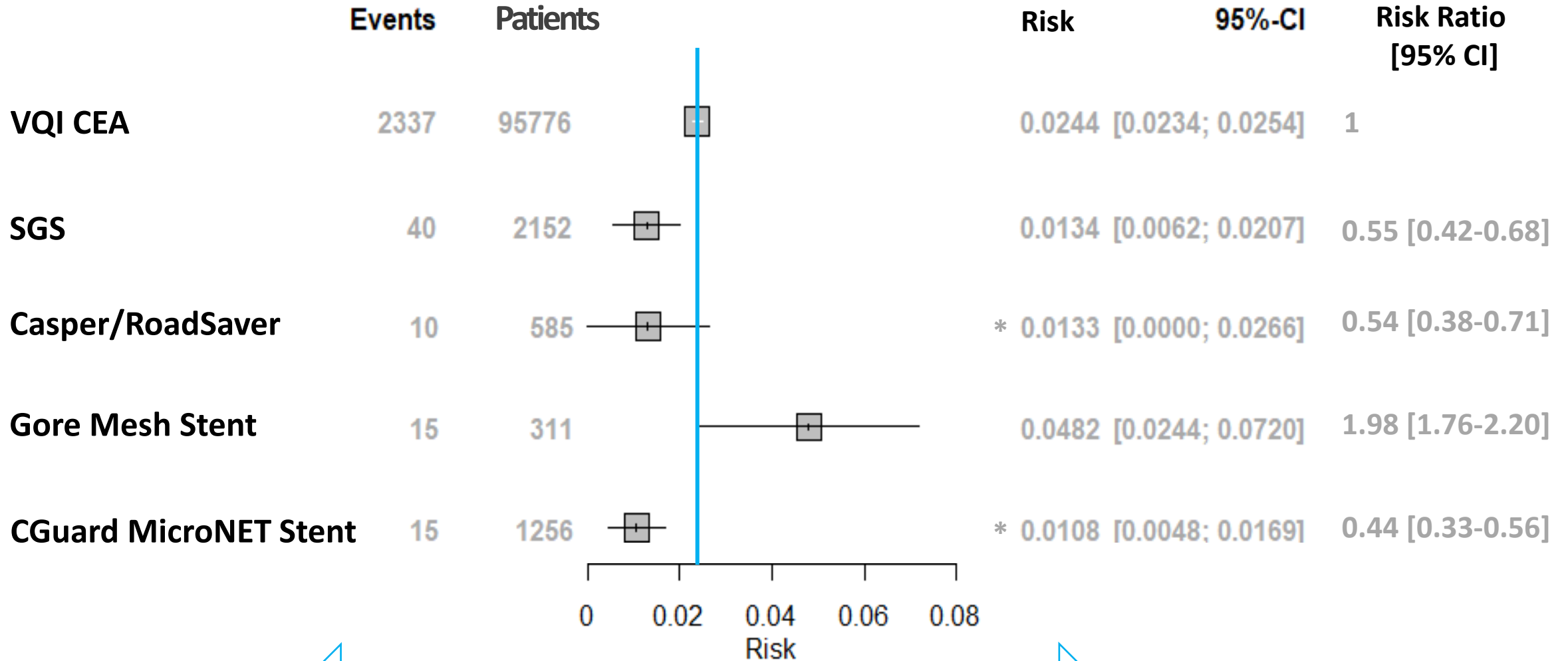
**FGS** – first generation stents; **SGS** – second generation stents (mesh/dual-layer)

\* as per published characteristics of study patients

# 30-day Death/Stroke/MI: RCT CEA vs SGS



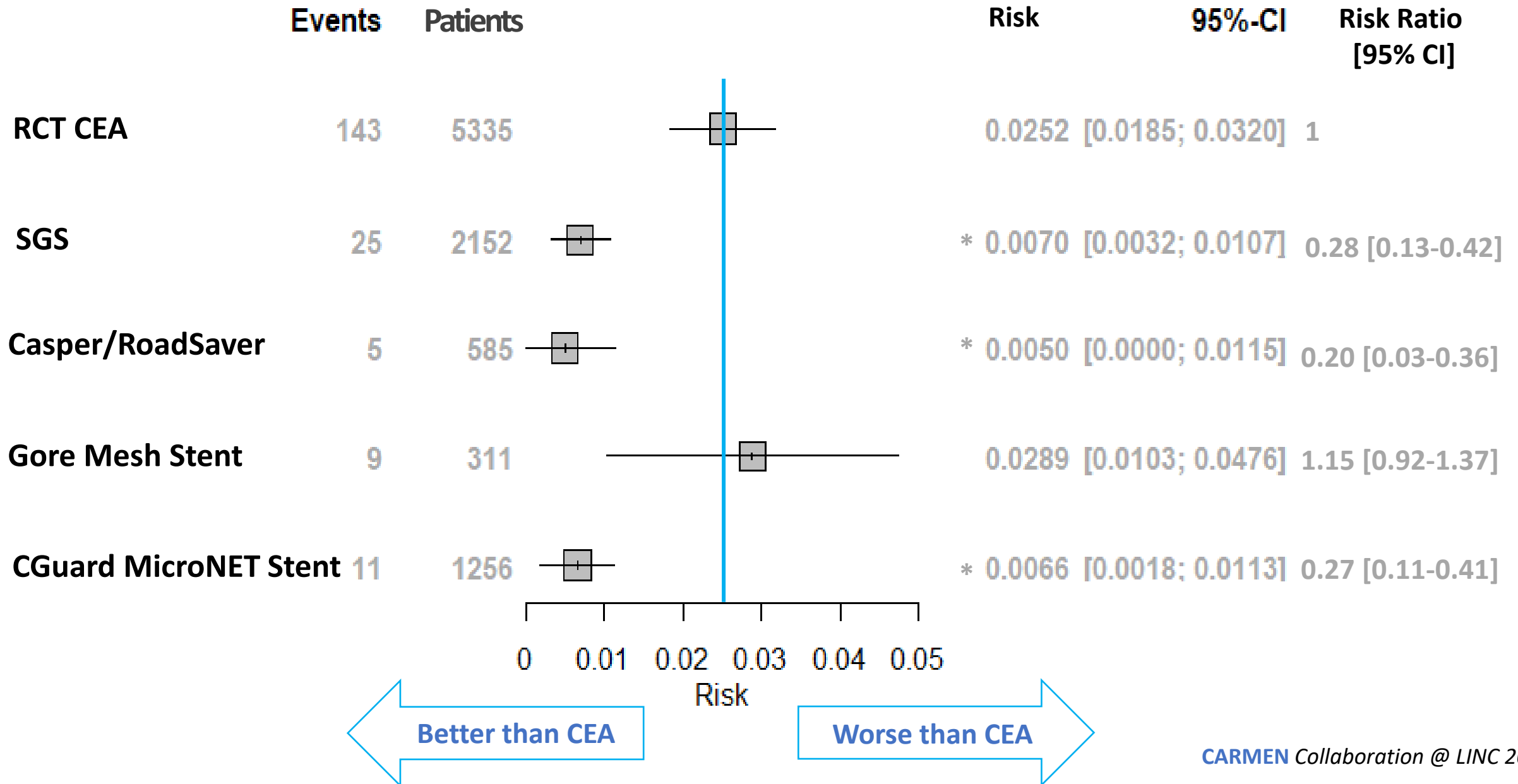
# 30-day Death/Stroke/MI: VQI CEA vs SGS



Better than CEA

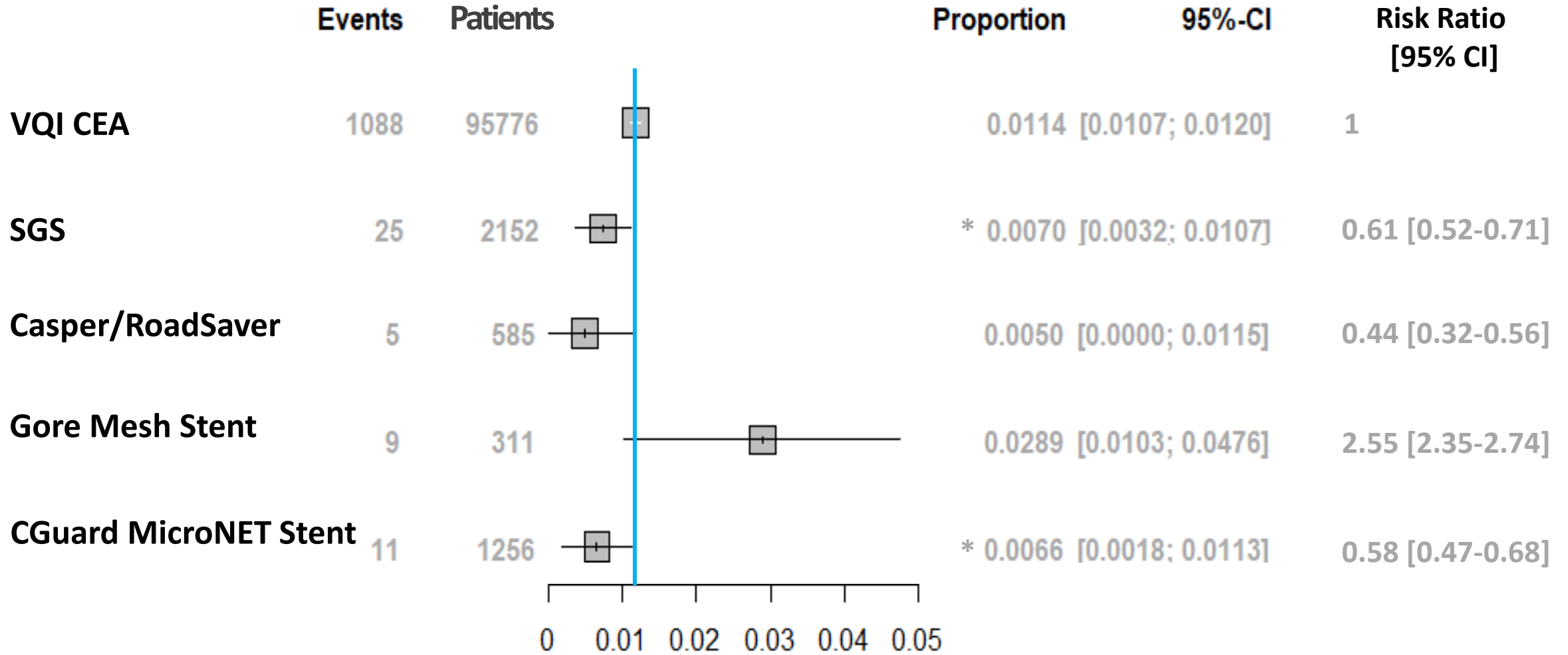
Worse than CEA

# 30-day Stroke: RCT CEA vs SGS





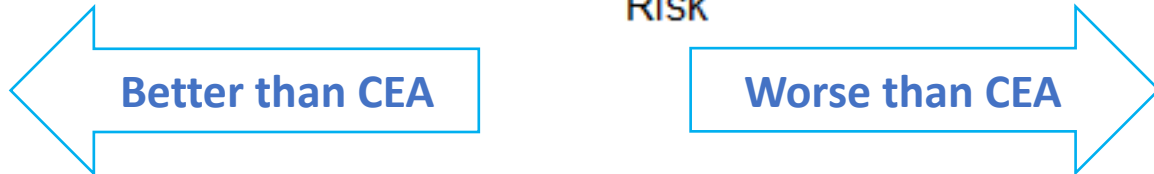
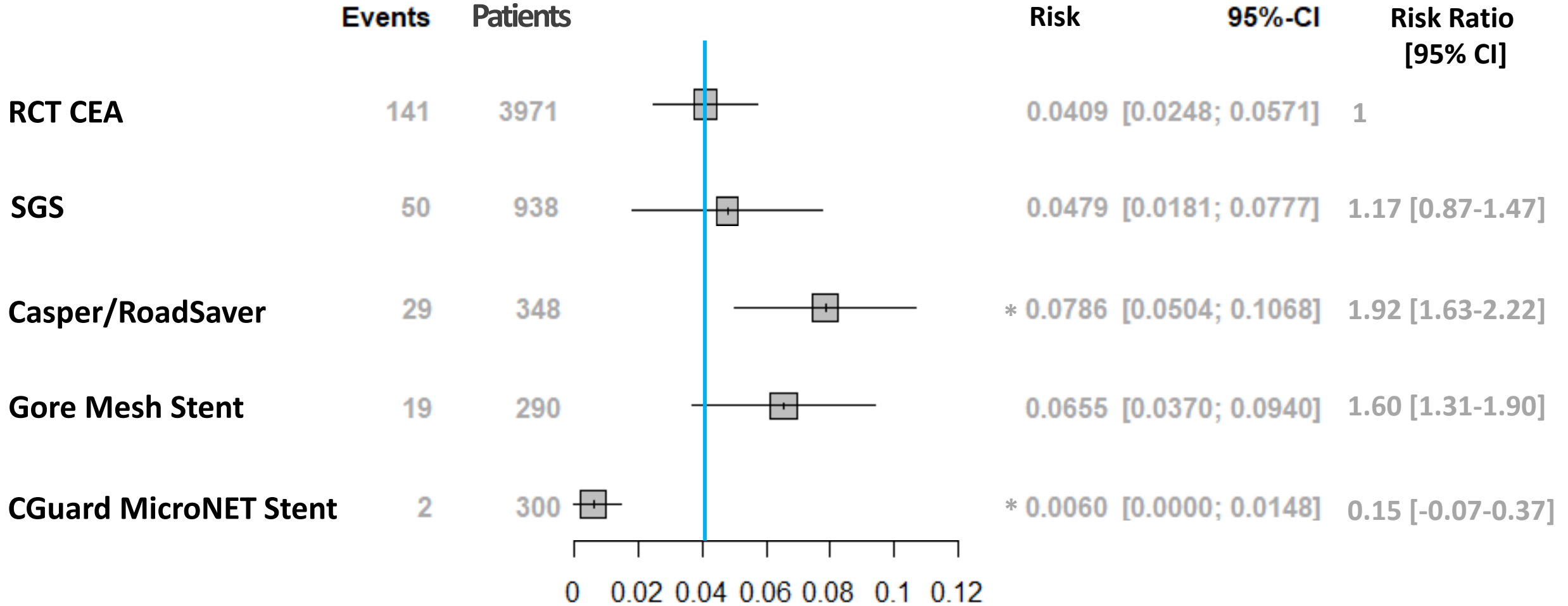
# 30-day Stroke: VQI CEA vs SGS



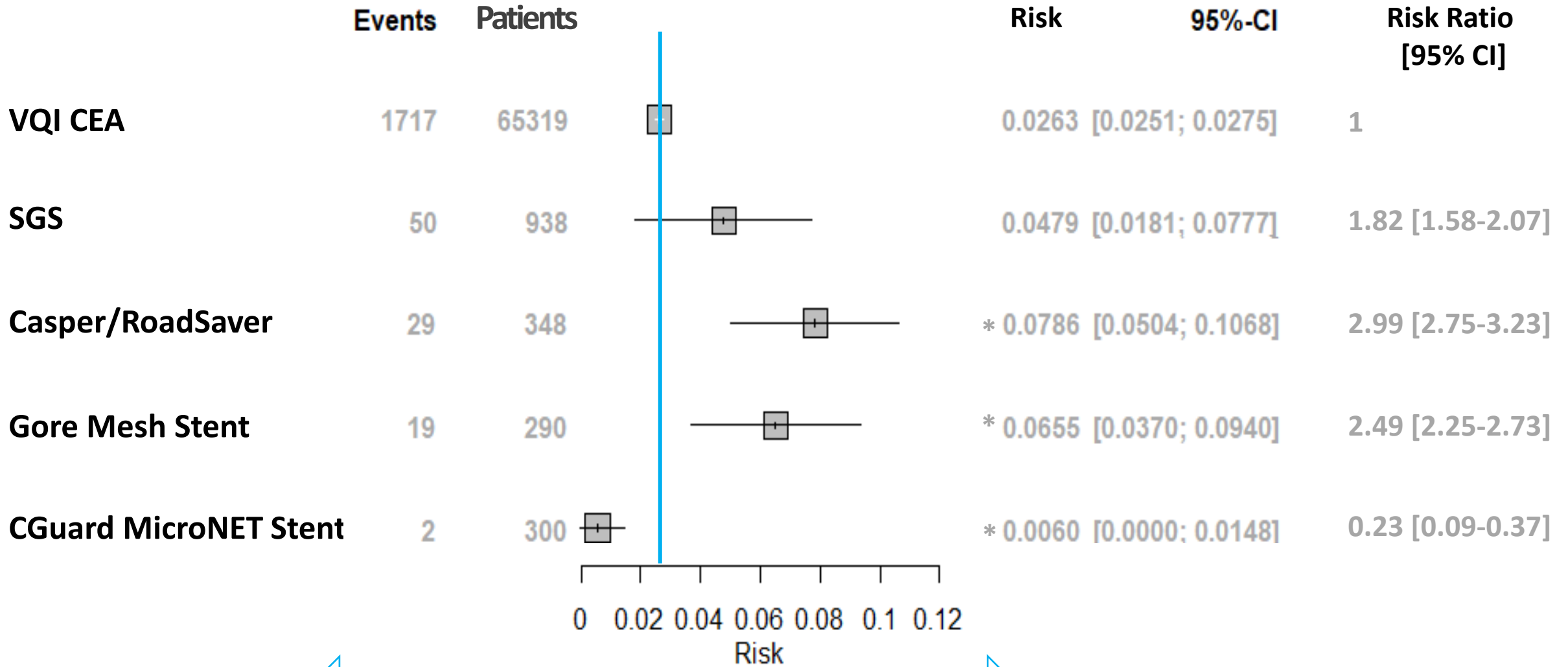
Better than CEA

Worse than CEA

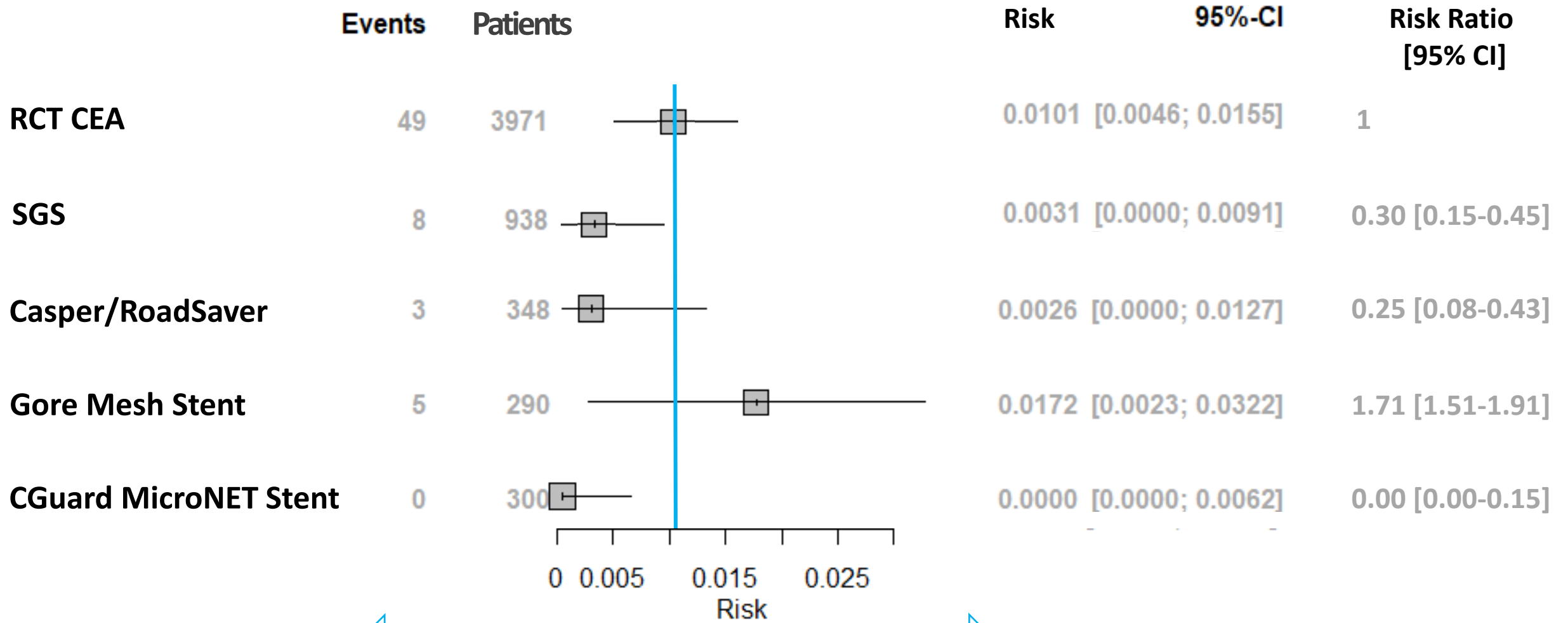
# 1-year Ipsilateral Stroke/Restenosis: RCT CEA vs SGS



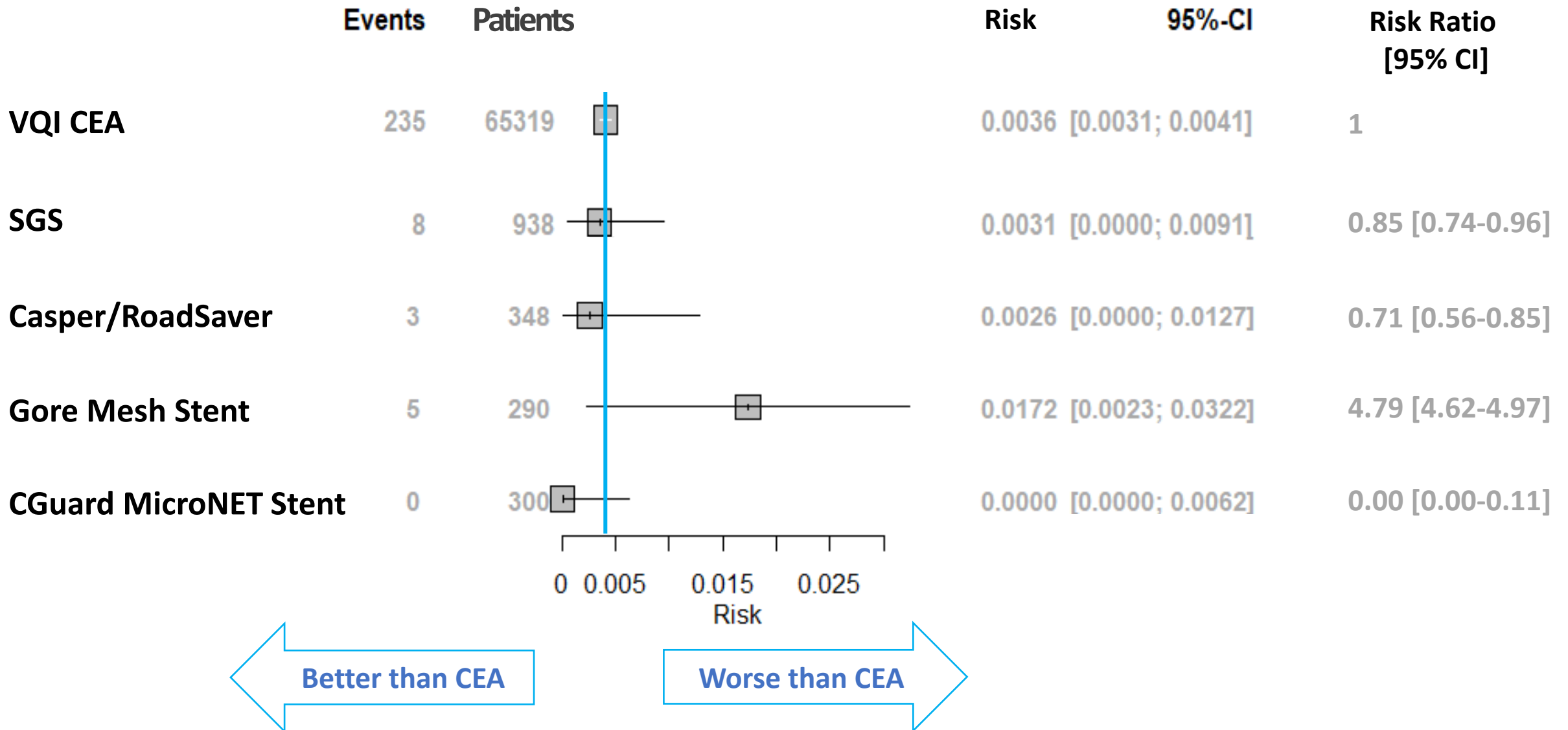
# 1-year Ipsilateral Stroke/Restenosis: VQI CEA vs SGS



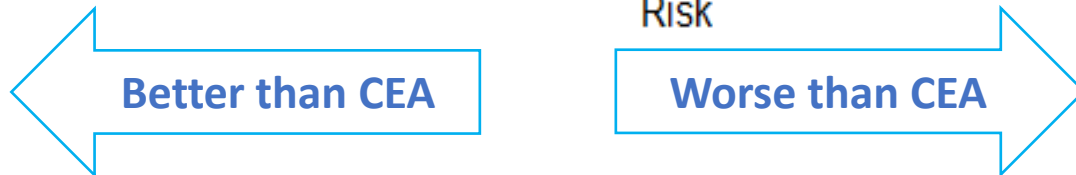
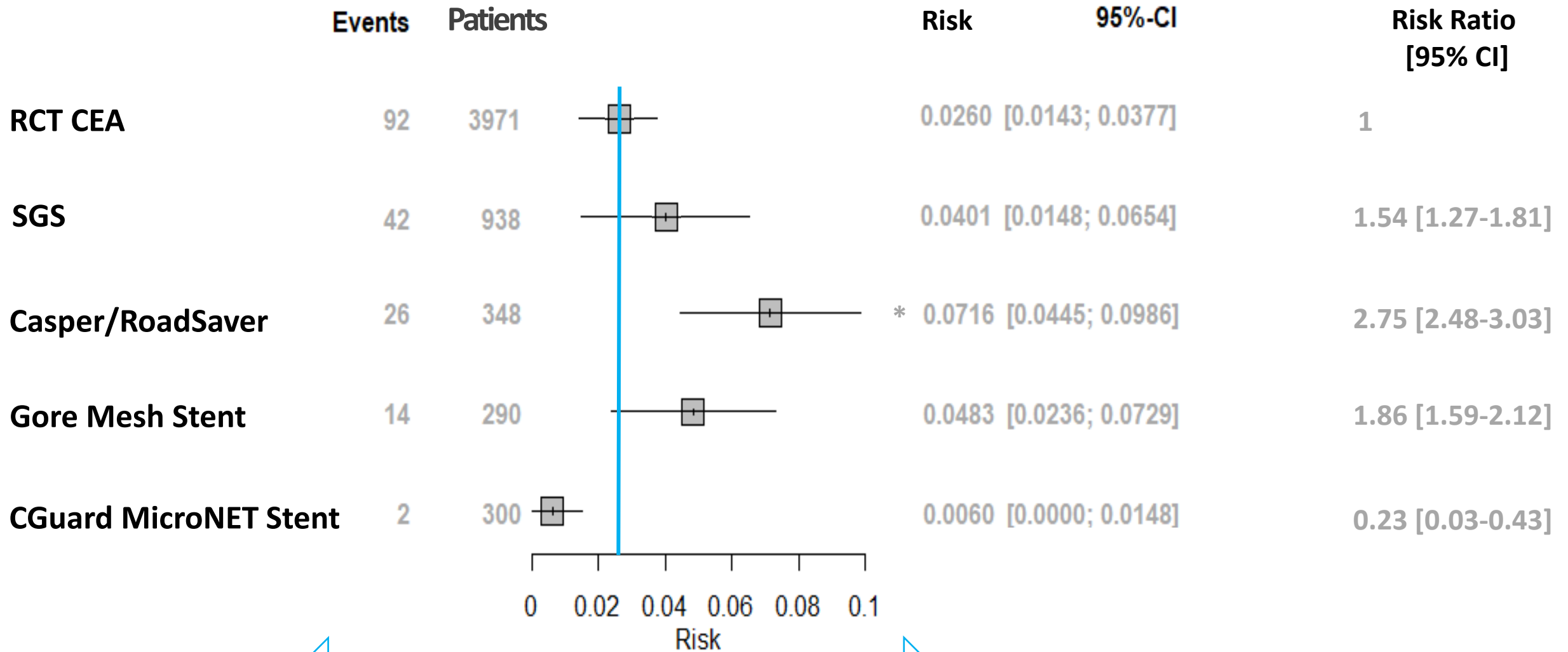
# 1-year Ipsilateral Stroke: RCT CEA vs SGS



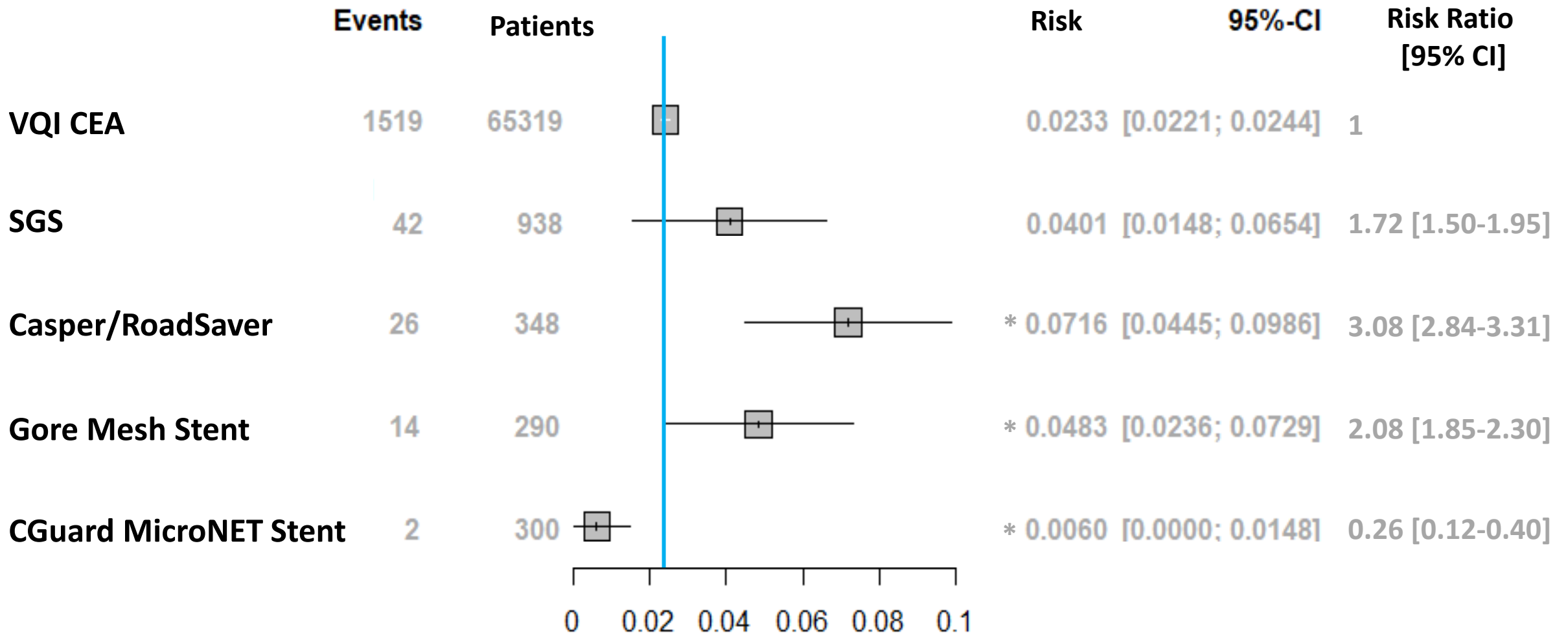
# 1-year Ipsilateral Stroke: VQI CEA vs SGS



# 1-year Restenosis: RCT CEA vs SGS



# 1-year Restenosis: VQI CEA vs SGS



# Conclusions: 30-day outcomes

- ***Casper/RoadSaver and CGuard MicroNET Stent*** superior to FGS as a group  
(and superior to both open- and close-cell stents)
- **↓ stroke with *Casper/RoadSaver* and ↓ stroke with *CGuard MicroNET Stent***  
vs RCT-CEA and VQI-CEA
- **NO class-effect** of SGS in relation to FGS or CEA



# Conclusions: 12-month outcomes

- **SGS superior to FGS**

*outcome driven by*      ↓ *in ipsi stroke with CGuard MiroNET Stent*  
   ↓ *in restenosis with CGuard MiroNET Stent*

- **SGS similar to CEA in 12-month ipsilateral stroke**

- **SGS have a differential effect on restenosis** in relation to CEA

↑ *restenosis with Casper/RoadSaver and Gore Stent*

↓ *restenosis with CGuard MicroNET Stent*

- **NO class-effect in SGS**