A Systematic Review of Economic Evaluations of Balloons and Stents for Patients With Coronary Artery Disease Undergoing Percutaneous Coronary Intervention

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BACKGROUND

- Balloons and stents(BAS) are usually used in Percutaneous coronary intervention (PCI) for the treatment of coronary artery disease (CAD).
- **Medical devices** including BAS are **more complex** than pharmaceuticals, their economic evaluation needs to consider the **distinctive characteristics**.
- Based on the previous studies, the **distinctiveness of medical devices** mainly includes
  1) **incremental innovation** (i.e. innovation often happens in small but fast steps),
  2) **dynamic pricing** (i.e. the price is rapidly changing over time),
  3) **learning curve effects** (i.e. medical outcomes are related to initiation or training period of learning how to make best use of the medical device),
  4) **organizational impact** (i.e. medical devices have a greater potential to indirectly impact an organization like patient treatment pathways, hospital workflows or staff training plan),
  5) **low evidence** (i.e. medical devices lack high-quality evidence) and
  6) **diversity** (medical devices cover a wide variety of products).

OBJECTIVES

- To identify the content and special considerations of existing economic evaluation methodologies regarding BAS for patients with CAD undergoing PCI.
- To explore how better to address the problems presented by BAS compared with drugs.

Methods

- **Systematic review** following six steps recommended in the International Society of Pharmacoeconomics and Outcome Research (ISPOR) guideline was performed.
- Reporting was performed on the basis of the **Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) and ISPOR CiCERO checklists.**
- Reporting quality of included studies was assessed using the **Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Checklis.**
- Methodological quality of included studies was assessed using the **Quality of Health Economic Studies (QHES) Checklist.**
- **Narrative synthesis** was used to synthesize the distinct methodology regarding the BAS.

RESULTS

- After the screening, **21 articles were included** in our systematic review. Figure 1 shows a PRISMA flowchart of the article selection process.

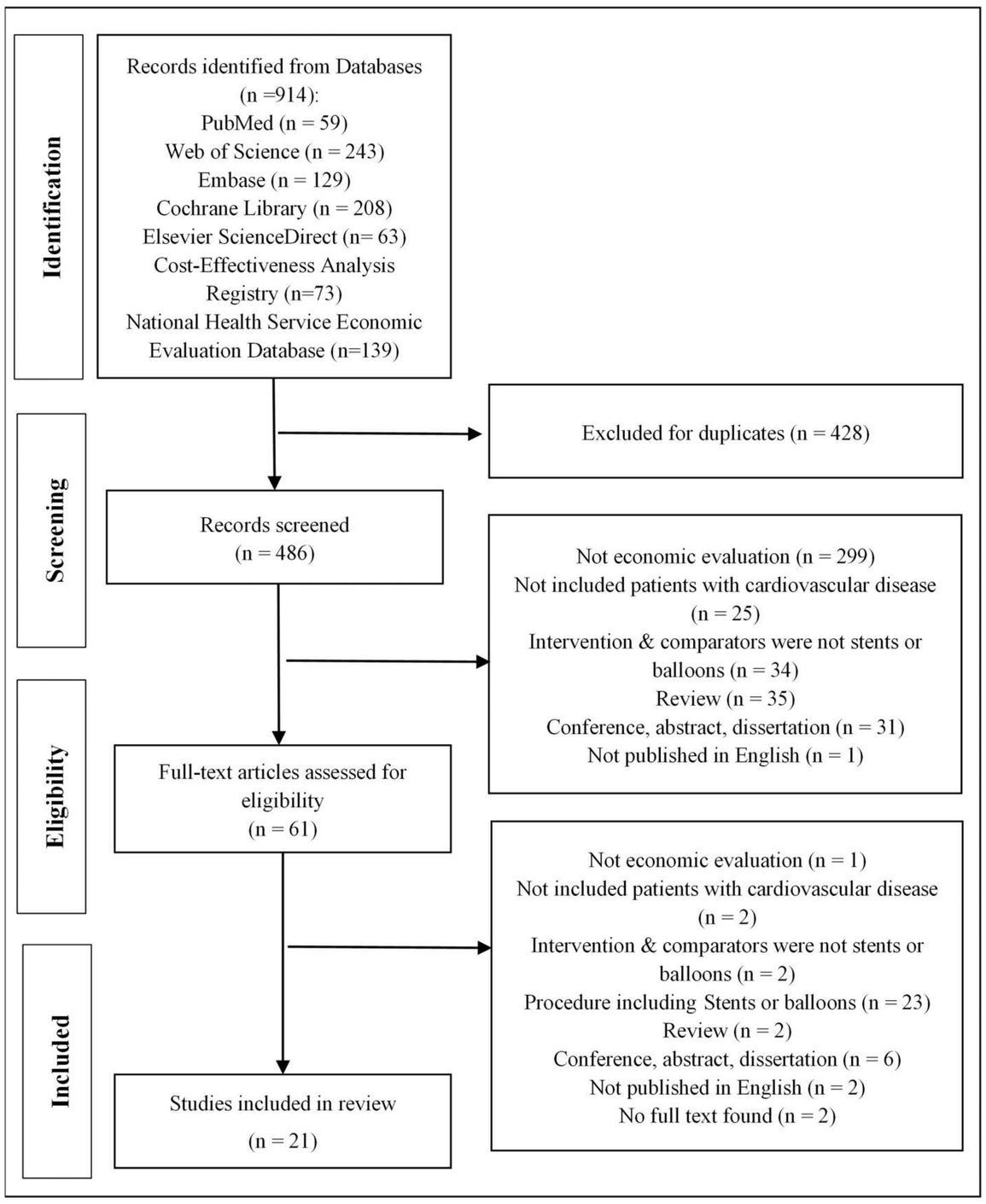

Figure1 PRISMA flow diagram for study selection process

- We found **quality of existing studies is low** and there is **no obvious difference** in the aspects of study perspective, comparator choice, modelling and data analysis approach between these studies and economic evaluations of drugs.
- **There are only a few special considerations and corresponding methodologies in existing studies:**
  1) Higher discount rate was used to reflect the rapidly changing prices of medical devices.
  2) The number of stents per procedure has a significant impact on health outcomes and costs.
  3) The length and diameter of the stent can affect clinical outcomes.

CONCLUSIONS

1) Existing economic evaluations of BAS for CADs did not comprehensively consider the distinctiveness.
2) The corresponding evaluation methods have not yet matured. Direct use of existing evidence may mislead related decision-makings.
3) **Innovative methods and high-quality evidence is urgently needed.**