REVIEW

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# Comparison of efficacy between cutting balloon and conventional balloon angioplasty for arteriovenous shunt stenosis: a meta-analysis

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## ABSTRACT

**Background:** Vascular access remains the main challenge in hemodialysis and is frequently complicated by stenosis and restenosis, necessitating effective interventions to maintain vascular patency. Cutting balloon angioplasty has emerged as a newer therapeutic modality. However, the effectiveness of cutting balloon angioplasty versus conventional balloon angioplasty is still an open question. This meta-analysis aims to provide an answer by collecting and analyzing the data available on the matter.

**Methods:** Cutting balloon and conventional balloon angioplasty were compared in studies only if they were randomized controlled trials; otherwise, the study was non-randomized if high-pressure balloon angioplasty, paclitaxel-coated balloon angioplasty, and vascular access stenting were used. A systematic search was conducted in the databases of PubMed, Scopus, and Web of Science, and the last search was done on August 16, 2025. The studies that were selected were analyzed for bias risk employing the RoB 2 tool. The RevMan 5.4 software was used for data analysis, and the results were given as forest plots.

**Results:** The final selection consisted of three randomized controlled trials that totaled 549 participants in the cutting balloon group and 536 in the conventional balloon group. The results showed that the target lesion at 6 months primary patency was higher for cutting balloon angioplasty than for conventional balloon angioplasty, with a relative risk of 1.21 (95% CI 1.03–1.40; p = 0.02). However, no significant differences in clinical and anatomical success were noted between the two groups (p>0.05).

**Conclusion:** The study had limitations due to the comparatively small sample size, which may lead to limited generalizability. However, it also gave an indication that cutting balloon angioplasty might be the better option for treating arteriovenous shunt stenosis.

**Keywords:** Arteriovenous Shunt Stenosis, Cutting Balloon, Conventional Balloon.
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## INTRODUCTION

Chronic Kidney Disease (CKD) is a global health problem with a prevalence reaching 9.1% in 2017, and this number continues to increase every year.[1] In Indonesia, the results of the 2023 Indonesian Health Survey (SKI) show that approximately 3.28 million residents aged >15 years suffer from CKD, with 314,690 of these patients undergoing routine hemodialysis.[2] CKD places a significant economic burden. This is because CKD patients spend IDR 1.9 - 2.2 million per session or more than IDR 200 million per patient per year just for routine hemodialysis. This financial burden increases further when the vascular access used, primarily the arteriovenous fistula (AVF), experiences complications such as stenosis or restenosis, which are major causes of morbidity in hemodialysis patients.[3] This situation requires additional interventions such as fistulography (IDR 2.3–2.7 million), angioplasty (IDR 6–8.5 million), and even stent placement (IDR 9.5–14 million), significantly adding to the total cost of care. Therefore, the problem of vascular access stenosis in CKD patients not only reduces quality of life and increases mortality but also worsens the economic burden on the national healthcare system.

Numerous procedures have been used to solve vascular stenosis for hemodialysis up to now, such as High-Pressure Balloon Angioplasty, Paclitaxel-Coated Balloon Angioplasty, and Cutting Balloon Angioplasty (CBA). However, there is still no consensus on the superiority of cutting balloon angioplasty over conventional angioplasty. Hence, this meta-analysis aims to collect and evaluate the existing studies to establish the place of cutting balloon angioplasty relative to conventional balloon angioplasty in terms of efficacy.

## METHODS

### Protocol Registration

This systematic review and meta-analysis followed the 2020 guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA).

The registration and acceptance of the protocol for this study have been done at PROSPERO with the identification number [CRD420245127630].

### Eligibility Criteria

This study's eligibility criteria were established by the PICOS framework with extra inclusion and exclusion criteria. The PICOS framework consists of the following components: [P]atients, Patients with Arteriovenous Shunt Stenosis; [I]ntervention, Cutting Balloon Angioplasty; [C]omparator, Conventional Balloon Angioplasty; [O]utcome, Clinical Success, Anatomical Success, Patency. The criteria for inclusion were: (1) Randomized Controlled Trial, (2) Study Comparing Cutting Balloon Angioplasty and Conventional Balloon Angioplasty. The criteria for exclusion were: (1) High-Pressure Balloon, (2) Paclitaxel-Coated Balloon, (3) Vascular Access Stenting.

Studies meeting the eligibility criteria were grouped for synthesis according to the predefined outcomes, including clinical success, anatomical success, and 6-month primary patency of the target lesion. Separate meta-analyses were performed for each outcome using only studies that reported extractable data for the respective outcome.

### Information Sources and Search Strategy

Four authors (MILB, MIQB, BM, and MDH) systematically searched the literature on PubMed, Scopus, and Web of Science Core Collection using the keywords "Arteriovenous Shunt Stenosis"; "Cutting Balloon Angioplasty"; "Conventional Balloon Angioplasty". The literature search was last updated on August 16, 2025. For the articles that met the eligibility criteria, a search through their reference lists was conducted to identify additional literature.

### Selection Process

Rayyan AI was employed to eliminate duplicates. After that, four independent reviewers (MILB, MIQB, BM, and MDH) performed the title/abstract and full-text screening of the articles. Every disagreement was talked over until a compromise was settled. The whole literature search process of the PRISMA workflow is shown in **Figure 1**.

### Data Collection Process and Data Items

Data extraction will be performed by four independent reviewers (MILB, MIQB, BM, and MDH), and any discrepancies will be discussed until a consensus is reached. The data that will be taken out consist of the following: author and year of publication; the location of the study; characteristics of the subjects (Age, Gender); and Outcome. More specifically, the definitions of the outcomes for this study are presented in **Table 1**.

When outcome data or study characteristics were missing or unclear, the available information reported in the original articles was used, and no additional assumptions were made unless explicitly stated.

### Study risk of bias assessment, reporting bias assessment, and certainty assessment

Four authors (MILB, MIQB, BM, and MDH) independently assess risk of bias using RoB 2; any disagreements were discussed until consensus was reached. The assessment was done with the conclusion of Low, Some Concern, and High Risk (**Supplementary Data 1**). Reporting bias was assessed using funnel plot analysis, with Egger's test subsequently performed to evaluate the presence of potential publication bias when more than ten studies were available for each group, in accordance with the recommendations of the Cochrane Handbook. Conclusions were presented using a summary plot and a traffic plot. Quality assessment for the result was assessed using GRADE (Grading of Recommendations

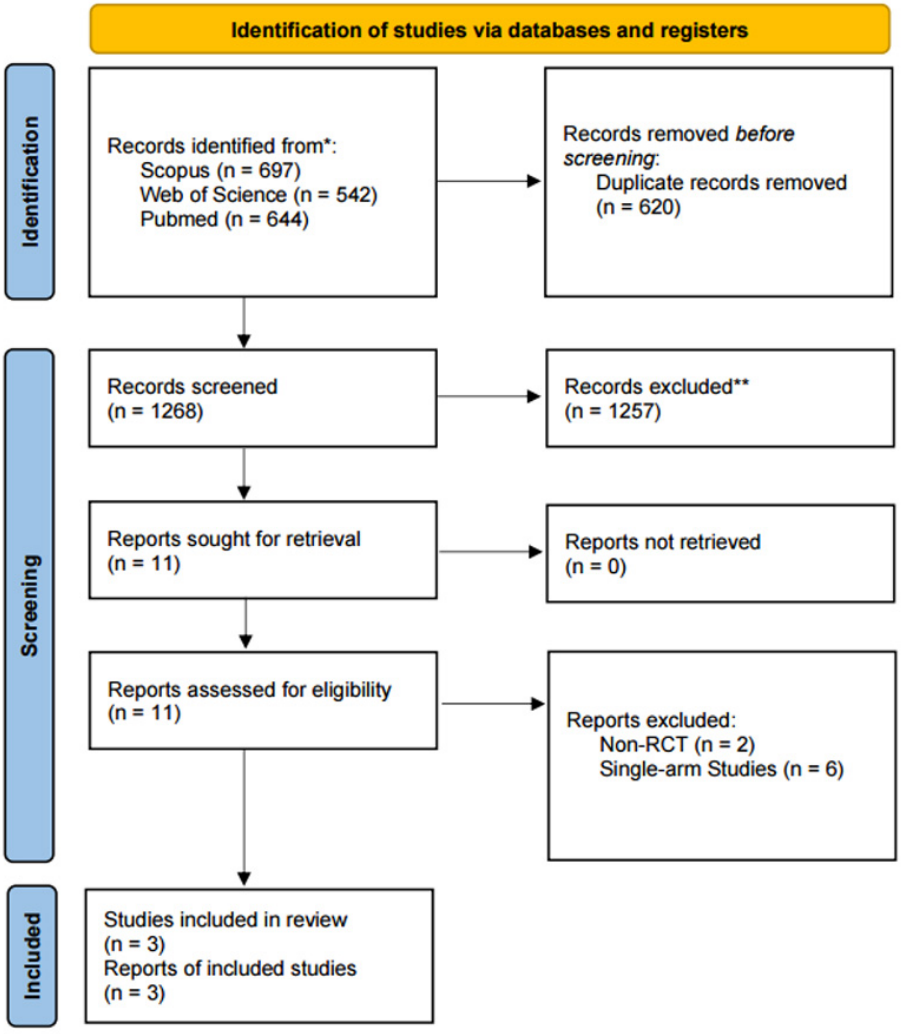


**Figure 1.** PRISMA Flowchart

Assessment, Development and Evaluation) (**Supplementary Data 2**).

### Effect Measure and Synthesis Methods

Studies that fulfilled the PICO criteria were summarized in tables according to their characteristics and reported outcomes, including clinical success, anatomical success, 6-month primary patency of the target lesion, and complications. Studies lacking extractable or comparable data for a particular outcome were excluded from that specific synthesis but were still considered for other applicable analyses.

Data conversion was performed to enable data synthesis. Data reported as percentages were converted into absolute values (number of subjects) by multiplying the percentages by the total population of each study, followed by rounding.

Data synthesis was done utilizing Review Manager Software (RevMan v5.4). For dichotomous data, we determined pooled estimates as risk ratios (RR) with 95% confidence intervals. The $I^2$ statistic was used to evaluate the degree of statistical heterogeneity, and an $I^2$ of 0-40% was considered to indicate a low level of heterogeneity. Meta-analysis of studies with low heterogeneity was conducted using a fixed-effect model, whereas a random-effects model was applied for studies with high heterogeneity. In addition, sensitivity analysis was performed using the trim-and-fill method by Duval and Tweedie if the heterogeneity was determined to be medium or high. Results from individual studies and pooled analyses were displayed in summary tables and forest plots.

## RESULTS

### Study Selection and Study Characteristic

The first step in the literature search resulted in an overall count of 1,883 studies, consisting of 644 studies from PubMed, 697 studies from Scopus, and 542 from Web of Science. After removing duplicates and screening titles/abstracts, 11 studies were selected for full-text evaluation. Three studies only were included in the analysis after the exclusion of eight studies: two were not randomized controlled trials (RCTs), and six were without a control group. The procedure for selecting studies is explained in a PRISMA flowchart in **Figure 1**.

A total of three RCTs, comprising 1,085 participants, were included in the meta-analysis. Study characteristics such as age and gender were generally comparable between the intervention and control groups. **Table 2** presents detailed study characteristics of the included studies.

### Risk of Bias and Quality Assessment

RoB 2.0 analysis showed 3 studies with some concerns. The studies with some concerns were caused by (1) Treating physicians were aware of the assigned intervention. (2) There was a deviation from the intervention, caused by some patients who did not achieve anatomic success or experienced complications, and they were immediately treated with another procedure, such as PTA or stent placement. The bias of the studies is revealed in **Supplementary Data 1**. According to the GRADE Assessment (**Supplementary Data 2**), the effectiveness of cutting balloons for arteriovenous shunt stenosis was supported by a very high level of certainty regarding the evidence.

This analysis included three studies, with a total of 1,085 patients (549 in the Cutting Balloon group and 536 in the Conventional Balloon group) reporting data on Clinical Success. All studies had some concerns regarding the risk of bias. The level of heterogeneity was very low

**Table 1. Outcome Definition**

| Outcome | Definition |
|---|---|
| Clinical Success | The clinical success was regarded as the resumption of at least one session of normal dialysis after angioplasty.[5] |
| Anatomical Success | The anatomical success was regarded as achieving the pre-defined threshold of less than 30% residual stenosis in the treated lesion.[6] |
| Primary Patency of the Target Lesion | The primary patency of the target lesion was defined as the period from the time of PTA until either thrombosis or any intervention in the treatment area occurred for the first time.[6] |

**Table 2. Study Characteristic**

| Author, Year | Location | Sample | | Age | | Gender | | Outcome |
|---|---|---|---|---|---|---|---|---|
| | | CBA | PTA | CBA | PTA | CBA | PTA | |
| Murakami et al., (2025)[6] | Japan | 60 | 62 | 72,3 ± 10,6 | 72,1 ± 9,5 | 39/21 | 46/16 | Clinical Success, Anatomical Success, 6 Month Primary Patency of Target Lesion, Primary Patency of Access Circuit |
| Saleh et al., (2014)[5] | Egypt | 316 | 307 | 60,4 ± 10 | 61,9 ± 10 | 185/131 | 137/170 | Clinical Success, 6 Month Primary Patency of Target Lesion |
| Vesely et al., (2005)[7] | US | 173 | 167 | 61.4 ± 14.3 | 63.4 ± 15.2 | 73/100 | 72/95 | Clinical Success, Anatomical Success, 6 Month Primary Patency of Target Lesion, Primary Patency of Access Circuit |

($I^2$ = 0%). The analysis yielded a risk ratio (RR) for Clinical Success of 1.02 (95% CI 0.98–1.06; p = 0.38), indicating no statistically significant difference between the two intervention groups (**Figure 2**).

This analysis included two studies, with a total of 462 patients (233 in the Cutting Balloon group and 229 in the Conventional Balloon group) reporting data on Anatomical Success. Both studies had some concerns regarding the risk of bias. The analysis showed a moderate level of heterogeneity ($I^2$ = 70%); however, a trim-and-fill analysis was not performed due to the limited number of studies. The analysis yielded a risk ratio (RR) for Anatomical Success of 1.15 (95% CI 0.82–1.62; p = 0.41), indicating no statistically significant difference between the two intervention groups (**Figure 3**).

This evaluation involved three separate studies that cumulatively researched 1,085 patients, 549 of whom belong to the Cutting Balloon group, while the other 536 are from the Conventional Balloon group. The studies reported data on the 6-Month Patency Rate. However, all three studies raised some concerns about the risk of bias. The heterogeneity among the studies was very low ($I^2$ = 30%). As a result of this analysis, a risk ratio (RR) for the 6-Month Patency Rate of 1.21 (95% CI 1.03-1.40; p = 0.02) was obtained, which points to a statistically significant advantage for the Cutting Balloon group (**Figure 4**).

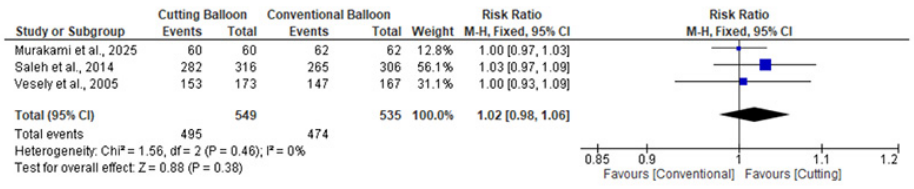


**Figure 2.** Clinical success evaluation

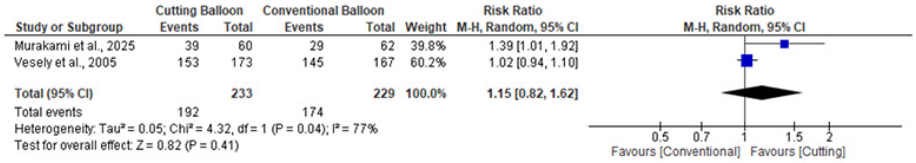


**Figure 3.** Anatomical success evaluation

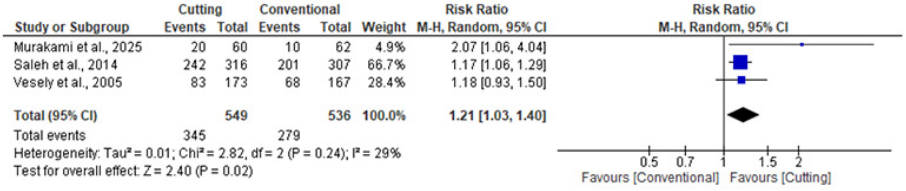


**Figure 4.** 6-Month Primary Patency of Target Lesion

## DISCUSSION

This meta-analysis shows that the use of cutting balloon provides a better six-month target lesion patency rate compared to conventional balloon angioplasty. This difference in outcomes is believed to be related to the design of the balloon used. Conventional balloons tend to cause irregular intimal tears, thereby triggering neointimal hyperplasia. In contrast, the cutting balloon is equipped with three to four longitudinally arranged atherotomes, which allow for more controlled dilation of the vessel lumen.[8,9]

In addition to differences in balloon design, inflation pressure characteristics are also an important factor. In this article, the use of conventional balloons and high-pressure balloons is distinguished based on the maximum pressure they can deliver. A high-pressure balloon is defined as a balloon with a pressure >20 atm, whereas an ultra-high-pressure balloon can achieve a pressure >30 atm.[10–12] However, all studies included in this meta-analysis used balloon inflation pressures <20 atm. Therefore, the comparisons made essentially remain within the range of conventional balloon pressures.

This limitation becomes increasingly relevant given the rapid advancement of endovascular technology in recent years. Various newer modalities—such as drug-coated balloons, ultra-high-pressure balloons, and stent placement—have been used in the management of AV shunt stenosis.[13–15] However, these therapies were not the focus of the included studies. Consequently, the results of this meta-analysis do not fully reflect the spectrum of contemporary endovascular treatment options.

In addition to limitations related to technological advancements, this study also has several methodological limitations that warrant attention. The number of included studies is relatively small, comprising only three randomized controlled trials, thereby limiting statistical power and making the meta-analysis results more susceptible to the findings of a single study. All the studies that were part of the analysis have a risk of bias. The major reason for this is that it was not possible to blind the practitioners who were performing the procedures. Clinical decision-making could have been swayed this way. Additionally, the applicability of the results might be restricted by differences between the places where the studies took place and the short duration of the follow-up. Therefore, it is not clear whether the benefits of cutting balloon angioplasty (CBA) will last in the long run.

Future research should focus on larger multicenter randomized controlled trials with longer follow-up periods to confirm the durability of the benefits associated with cutting balloon angioplasty (CBA). In addition, comprehensive cost-effectiveness analyses are needed to determine whether the improved patency outcomes justify the higher procedural costs. Future studies should also identify lesion characteristics that derive the greatest benefit from CBA and directly compare CBA with emerging endovascular technologies, such as drug-coated balloons, ultra-high-pressure

balloons, and stent-based interventions, to better define the optimal treatment strategy for hemodialysis access stenosis.

Considering the findings and the various existing limitations, CBA in clinical practice should be positioned as a selective interventional modality, not as a universal replacement for percutaneous transluminal angioplasty (PTA). CBA is a rational choice, particularly in challenging stenosis cases such as recurrent stenosis, where extending the interval until the next intervention is the primary goal. Its comparable safety profile to PTA makes CBA clinically appealing. At the same time, its higher cost implications need to be proportionally weighed against its potential to reduce the need for repeat interventions and maintain dialysis access patency. Overall, these findings can serve as a basis for clinical decision-making, the development of practice guidelines, and the evaluation of healthcare financing policies in the future.

## CONCLUSION

This meta-analysis suggests that cutting balloon angioplasty (CBA) provides superior 6-month primary patency of the target lesion compared with conventional balloon angioplasty in patients with arteriovenous shunt stenosis. However, no significant differences were observed in clinical success or anatomical success between the two approaches. Although the available evidence indicates a potential advantage of CBA in maintaining vascular access patency, the findings should be interpreted cautiously because of the limited number of studies and relatively short follow-up durations. Larger randomized controlled trials with longer follow-up are needed to confirm the long-term effectiveness and cost-effectiveness of CBA in the management of hemodialysis access stenosis.

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## CONFLICT OF INTEREST

There is no conflict of interest regarding manuscript.

## DATA AVAILABILITY

The datasets generated and analyzed in this study are available in the Zenodo repository (https://zenodo.org/doi) (https://doi.org/10.5281/zenodo.18296544)

## AUTHOR CONTRIBUTION

MIB was the one who conceived, created, and had the overall control over the manuscript. All the co-authors carried out the study. MIB is the one who performs the data analysis. Each of the authors contributes to the writing of the manuscript and consents to the submission of this final version to this periodical.

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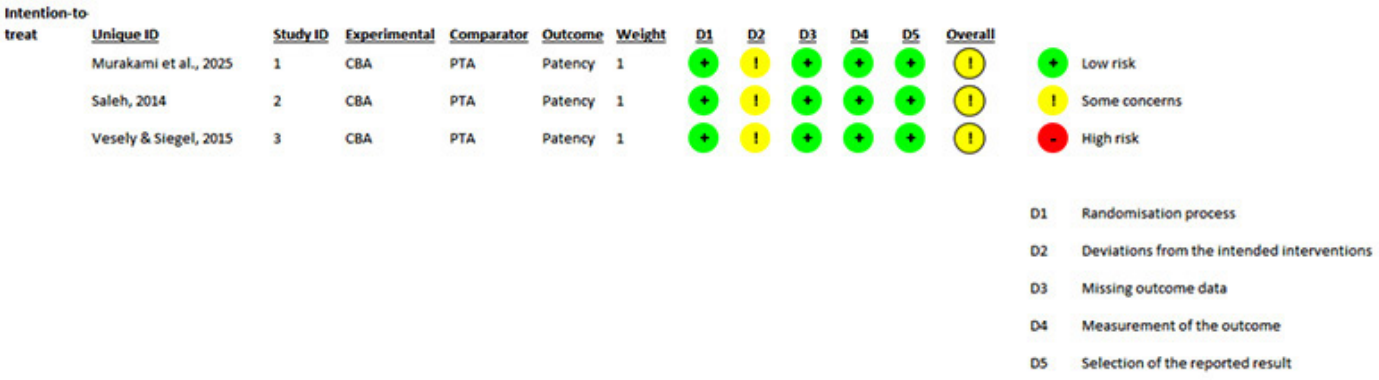
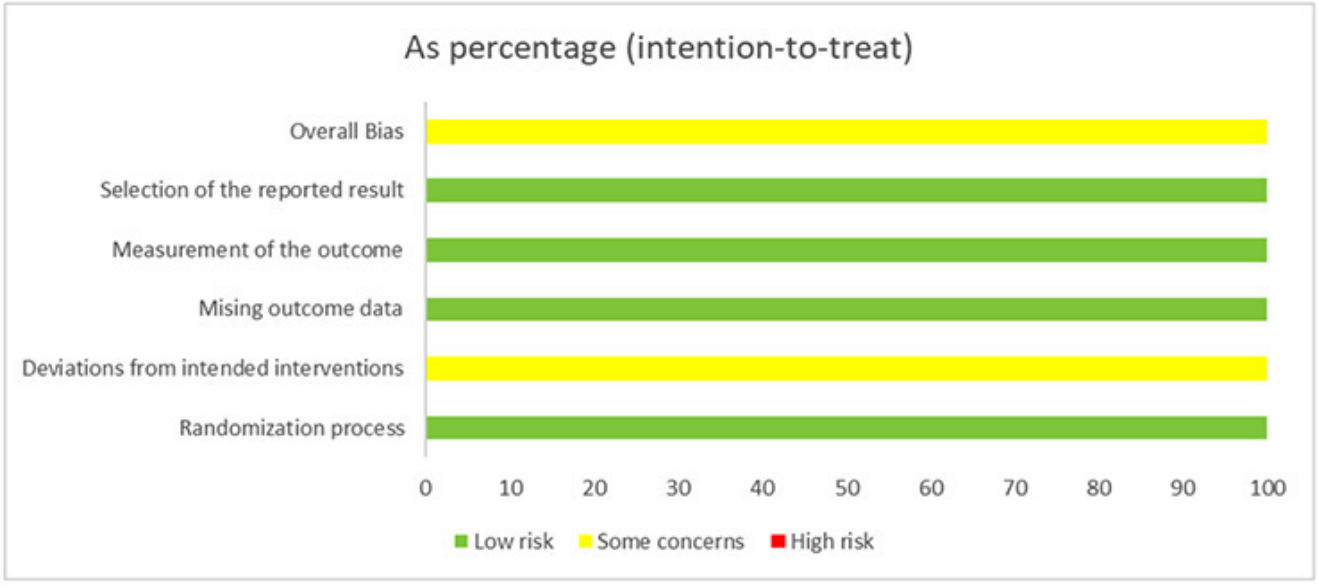
## Supplementary Data 1. Risk of Bias



**Supplementary Data 2. GRADE Assessment**

| No of studies | Certainty assessment | | | | | | Effect | | | Certainty | Importance |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations (Associations) | No of events | No of individuals | Rate (95% CI) | | |
| Clinical Success of Cutting balloon angioplasty compared to conventional balloon angioplasty | | | | | | | | | | | |
| 3 | RCT | All Study have Some Concern on Risk of Bias Assessment | not serious | not serious | not serious | | 969 | 1.085 | | Moderate (3 Star) | Critical |
| Anatomical Success of Cutting balloon angioplasty compared to conventional balloon angioplasty | | | | | | | | | | | |
| 2 | RCT | All Study have Some Concern on Risk of Bias Assessment | not serious | not serious | not serious | | 366 | 462 | | Moderate (3 Star) | Critical |
| 6-Month Primary Patency of Cutting balloon angioplasty compared to conventional balloon angioplasty | | | | | | | | | | | |
| 3 | RCT | All Study have Some Concern on Risk of Bias Assessment | not serious | not serious | not serious | | 627 | 1.085 | | Moderate (3 Star) | Critical |