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Egyptian Journal of Neurosurgery (2023) 38:57
https://doi.org/10.1186/s41984-023-00236-7

Egyptian Journal of Neurosurgery

REVIEW

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A systematic review and meta-analysis of Surpass flow diverter for the treatment of intracranial aneurysms

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Abstract

Objective Systematically review and analyze the published literature on the safety and efficacy of Surpass flow diverter in terms of mortality, functional outcome, complication rate, and aneurysm occlusion rate.

Methods The literature was searched in PubMed, MEDLINE, Embase, and Scopus using the terms *Surpass for the treatment of Intracranial aneurysms, Intracranial aneurysms, Complication* with no constraints applied. Two review authors independently conducted the study selection. Two review authors independently extracted study data. Data were pooled using a random effect model, results were abstracted as odds ratios and 95% CI, and heterogeneity was reported as I^2.

Results Five studies were included, which involved retrospectively and prospectively collected data on 464 patients. The use of Surpass flow diverter was associated with a rate of occlusion of 73.4% (95% confidence interval [CI] 62.48–83.077%). Low rate of thromboembolic complication was 6.6% (95% CI 3.0–10.1%), the rate of hemorrhagic complication was 2.9% (95% CI 1.6–4.6%), and low vasospasm rate was 4.38% (95% confidence interval [CI] 1.8–7.7%). The mortality rate was 4.6% (95% CI 1.4–1.4%). An overall of good outcome was 86.6% (95% CI 75.9–94.5%), and poor outcome was 7.8% (95% CI 5.0–11.2%).

Conclusions Based on the studies available in the literature, Surpass flow diverter offers high aneurysm occlusion rates with adequate safety and low rate of complications.

Keywords Surpass, Flow-diverting device, Intracranial aneurysm, Complication

Introduction

Intracranial aneurysms (IA) reach a prevalence of 5–10% of the world population [1]. The rupture of intracranial aneurysms is associated with high mortality and morbidity. For several decades, microsurgical management was the most popular strategy for resolutive treatment offered but with morbidity. The emergence of endovascular techniques has been a cost-effective alternative. Endovascular reconstruction for the treatment of IA with flow diverters (FDs) has represented a new paradigm in medicine [2, 3].

Worldwide, various flow diverters have been used to manage IA, including Silk (Balt), p64 (Phenox), Pipeline (Ev3), FRED (Microvention), among others. The Surpass flow diverter (SFD, Stryker, Neurovascular, Fremont, CA) is a new device approved by the FDA in 2018 [3]. It is a self-expandable tube (stent), cobalt chromium and

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platinum tungsten braided designed for the treatment of wide-neck aneurysms and intracranial fusiform aneurysms [3].

Several series have been published reporting the performance of the FD in the treatment of IA [4–8]. To date, no study has been published evaluating the safety and efficacy of Surpass flow diverter comprehensively. The purpose of this study is to investigate the outcome, overall complication rates, occlusion rate, retreatment, thromboembolic, and hemorrhagic complications for different patient cohorts treated with Surpass flow diverter.

Methods

This study was designed and conducted to define results regarding multiples outcomes after IA treatment using Surpass flow diverter.

Search

We used the search strategies recommended for the preferred reporting items for systematic reviews and meta-analyses (PRISMA) reporting guidelines and the meta-analysis of observational studies in epidemiology (MOOSE) reporting guidelines. Titles, abstracts, key words, and free text were searched using combinations of the following key words Surpass [All Fields] [All Fields] AND ("intracranial aneurysm"[MeSH Terms] OR ("intracranial"[All Fields] AND "aneurysm"[All Fields]) OR "intracranial aneurysm"[All Fields]). We searched PubMed, MEDLINE (Ovid), EMBASE, and Scopus from database inception to June 2023 for RCT, not RCT, prospective and retrospective cohort studies that reported data on the use of Surpass flow diverter for treatment of IA. We added studies from the reference list of included studies and other relevant data in addition to potentially eligible studies.

Inclusion and exclusion criteria

This analysis included: (1) studies on at least ten patients undergoing IA treatment with an FD; (2) studies with data on periprocedural and delayed complications; and (3) Only English language studies. In addition, the following were excluded: (1) studies that were not published in full; and (2) editorials, letters, review articles, guidelines, case reports, in vitro studies, and studies on animal experimentation.

Data collection process

Two review authors (L.R.M.S. and W.F.P.) independently extracted data from the included studies using a piloted data extracted form, resolving any discrepancies through discussion. We retrieved any articles identified as potentially relevant by at least one review author. Two review authors (L.R.M.S. and W.F.P.) independently screened full-text articles, with discrepancies resolved through discussion. The references of relevant studies were cross-checked for additional studies not identified by the electronic search.

Data extraction

Epidemiological data included were extracted: (1) study characteristics; (2) patient characteristics (number of patients, demographics, and clinical characteristics); (3) eligibility, based on the abovementioned study selection criteria; (4) mortality and morbidity; (5) adverse technical events; (6) We also categorized adverse procedural events as follows: symptomatic ischemic events, hemorrhagic events, and symptoms derived from mass effect. The doubts were clarified by consensus (Table 1).

Quality assessment and statistical analysis

We used statistics software (MedCalc version 19.03, London, United Kingdom) for the statistical analysis. We measured the outcomes by calculating proportions and 95% CIs for each study, then pooled the data to derive a pooled proportion and 95% CI; for this meta-analysis, we used Random effects models**.** Heterogeneity was assessed by calculating Chi-square (I^2), with a high heterogeneity of the studies included in the analysis being above 60%. The modified Newcastle–Ottawa scale (NOS) [7] was used for assessing the quality and risk of bias of the included studies. One reviewer (L.R.MS) assessed the quality of each study using this scale, and high, moderate, and low risk of bias were defined as NOS < 4, between 4 and 6, and > 6, respectively.

The Newcastle–Ottawa Scale assesses risk of bias in three domains: selection (representativeness and sample size), comparability (demonstration that result was not present at the start of the study, missing data or course of information, and confounding variable), and outcome (evaluation outcome and sufficient follow-up period). The risk of publication bias was further assessed using and comparing the Egger's test. A *P* value of less than 0.1 for Egger's test was considered statistically significant [9].

Results

Study selection

After conducting the systematic search of the information following our strategy, 100 bibliographic citations were identified, 50 were considered potentially eligible based on the title or abstract, or both, and the full texts. After a review of the full text, eight studies were considered eligible, three were ruled out because they did not meet the inclusion criteria and did not answer the research question, and five met the inclusion criteria for the review (Fig. 1) [10–14].

Table 1 Characteristics of studies included in the meta-analysis

Study	Type	Patients	Outcome	Length following
Wakhloo et al. [10]	Prospective observational Cohort	*N* = 190	Mortality Modified Rankin Scale Complete occlusion rate O'Kelly–Marotta Cy D. at end follow Complications thrombotic (stroke, transient ischemic attack and lacunar stroke) and hemorrhagic (ruptured aneurysm, intracerebral hemorrhage) Vasospasm (Cerebral angiography)	6 months
Taschner et al. [11]	Retrospective observational Cohort	*N* = 52	Mortality Modified Rankin Scale Complete occlusion rate O'Kelly–Marotta Cy D. at end follow Complications thrombotic (stroke, transient ischemic attack and lacunar stroke) and hemorrhagic (ruptured aneurysm, intracerebral hemorrhage) Vasospasm (Cerebral angiography)	11.3 months
Mahajan et al. [12]	Prospective observational Cohort	*N* = 16	Mortality Modified Rankin Scale Complete occlusion rate O'Kelly–Marotta Cy D. at end follow Complications thrombotic (stroke, transient ischemic attack and lacunar stroke) and hemorrhagic (ruptured aneurysm, intracerebral hemorrhage) Vasospasm (Cerebral angiography)	6 months
Meyers et al. [13]	Prospective observational Cohort	*N* = 180	Mortality Modified Rankin Scale Raymond classification A at end follow Complications thrombotic (stroke, transient ischemic attack and lacunar stroke) and hemorrhagic (ruptured aneurysm, intracerebral hemorrhage) Vasospasm (Cerebral angiography)	12 months
Orru et al. [14]	Retrospective observational Cohort	*N* = 26	Mortality Modified Rankin Scale Complete occlusion rate O'Kelly–Marotta Cy D. at end follow Complications thrombotic (stroke, transient ischemic attack and lacunar stroke) and hemorrhagic (ruptured aneurysm, intracerebral hemorrhage) Vasospasm (Cerebral angiography)	12 Months

Risk of bias and quality assessment

Among five included studies in the analysis, only two [11, 13] obtained the maximum score of 7, two [10, 14] obtained 6 points, and one [12] obtained 5 points on the scale used (See Additional file 1, Table 2). Mahajan et al. and Orru et al. were found to present a moderate risk of selection bias when presenting a small but representative sample. Wakhloo et al. and Majahan et al. present a moderate risk of outcome bias when presenting a strict follow-up of the patients without losses due to lack of follow-up or abandonment; however, the follow-up time was not short to demonstrate the expected outcomes. With all these exceptions, all studies showed low risk of bias in all domains in the Newcastle–Ottawa Scale. The funnel plot and the Egger's test for all predictors showed different grades of asymmetry, as exposed in Figs. 2 and 3.

Meta-analysis of included studies

Five studies were chosen for the final analysis, involving 464 patients. The statistical analysis was performed according to the protocol. Each variable is pooled in Figs. 4 and 5.

In the analysis of the clinical outcomes, the mortality rate, good and bad clinical prognosis, as well as the rate of complete occlusion or greater than 90% in patients with Surpass Device were evaluated. Obtaining the following results, a mortality of 4.96% (95% CI 1.439–10.442%) with included studies with high heterogeneity ($I^2 = 74.61\%$), good outcome of 86.642% (95% CI 75.997–94.519%; $I^2 = 85.86\%$), poor outcome of 7.887% (95% CI 5.076–11.253%; $I^2 = 24.92\%$), and complete occlusion rate of 73.424% (95% CI 62.48–83.077%; $I^2 = 80.36\%$), the studies for all the descendants showed a high heterogeneity; this is due to the effect of the studies small studies given by the studies Orru et al. [14] and Mahajan et al. [12].

Complications that were assessed in the included studies were thromboembolic complications, hemorrhagic complications, and vasospasm. Thromboembolic complications (stroke, pulmonary embolism, transient acute ischemic attack, etc.) occurred in 6.11% (95% CI

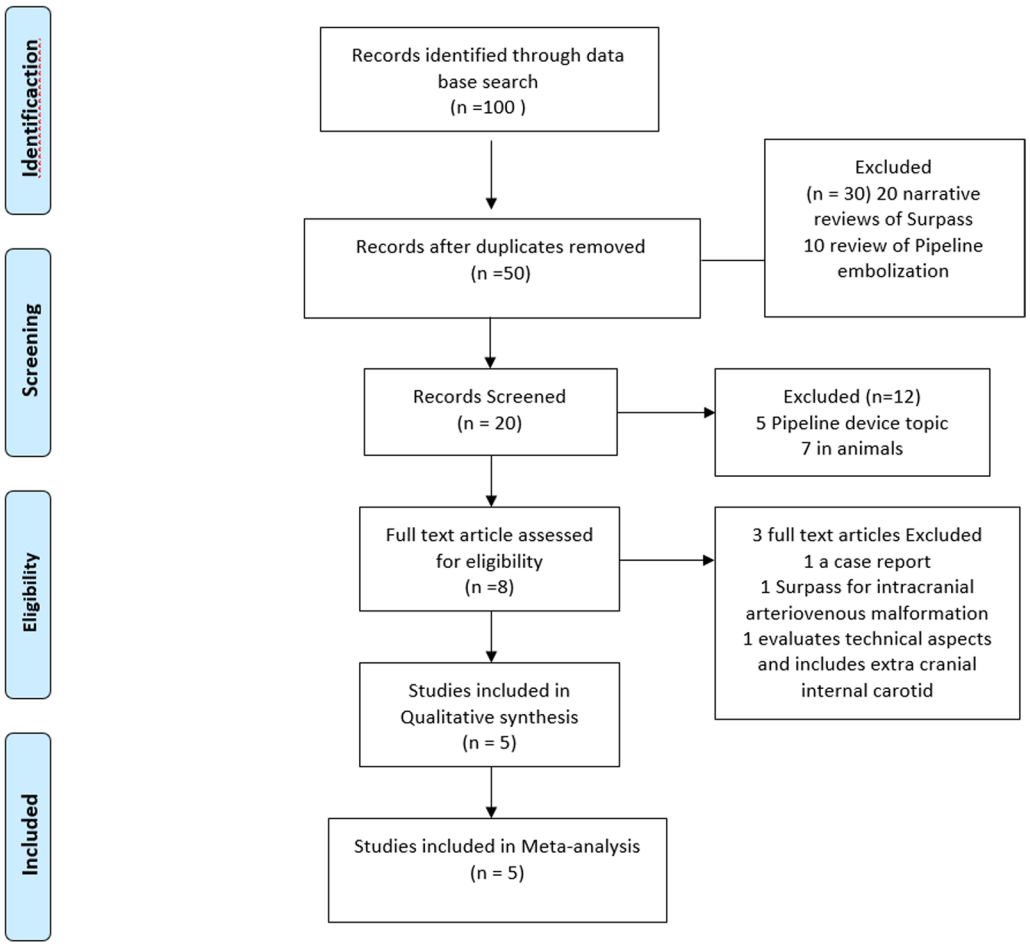

Fig. 1 Flow diagram of search and selection process

Table 2 Newcastle–Ottawa Scale for quality assessment of studies included in this meta-analysis

References	Representativeness of sample	Size sample	Source of information	Demonstration that outcome was not present at study start	Confusion variable control	Assessment of outcome	Enough follow-up period	Newcastle–Ottawa scale score
Wakhloo et al. [10]	★	★	★	★	★	★		6/7
Taschner et al. [11]	★	★	★	★	★	★	★	7/7
Mahajan et al. [12]	★		★	★	★	★		5/7
Meyers et al. [13]	★	★	★	★	★	★	★	7/7
Orru et al. [14]	★		★	★	★	★	★	6/7

★ Indicates that it meets criteria in Newcastle–Ottawa Scale

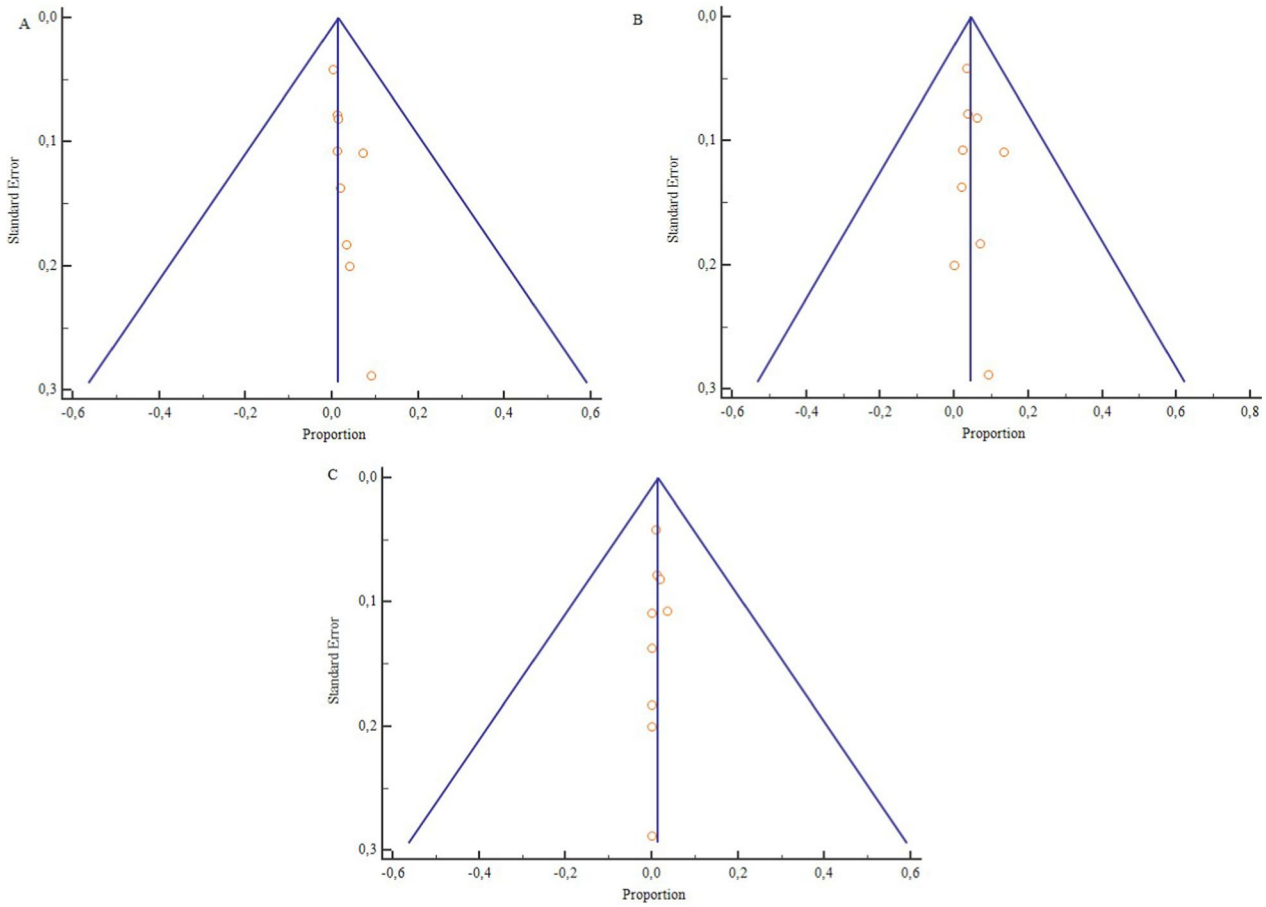

Fig. 2 Funnel plot assessing the risk of publication bias in outcomes: **A** Thromboembolic complication, **B** Hemorrhagic complication, **C** Vasospasm

3.071–10.102%) of patients with aneurysms treated with Surpass device with low heterogeneity between studies included ($I^2 = 49.69\%$) and intracranial bleeding of various types presented in 2.962% (95% CI 1.622–4.682%) with good homogeneity ($I^2 = 0.00\%$).

Discussion

Our systematic review and meta-analysis of five studies including 464 patients show that Surpass for intracranial aneurysms is associated with high rate of aneurysms occlusion and low rate of complications. The relevance of our research is that included all research papers until June 2023, and the last paper published was in 2020.

Wakhloo published in 2015 a study which was a prospective, multicenter study of the Surpass flow diverter for the treatment of intracranial aneurysms [10]. A total of 161 patients with 186 aneurysms were enrolled in the study. The primary outcome was technical success, defined as successful delivery of the flow diverter and complete occlusion of the aneurysm at the end of the procedure. The secondary outcomes included clinical outcomes, such as mortality and morbidity, and angiographic outcomes, such as aneurysm occlusion rate. The study found that the technical success rate was 98%. The clinical outcome at 6 months was also good, with a mortality rate of 2.7% and a morbidity rate of 6%. The angiographic outcome was also good, with a complete occlusion rate of 75% at 6 months.

The study concluded that the Surpass flow diverter is a safe and effective treatment for intracranial aneurysms. It is comparable to stent-assisted coil embolization in terms of safety and efficacy. Here are some of the key findings of the study: The technical success rate of the Surpass flow diverter was 98%, clinical outcome at 6 months was good, with a mortality rate of 2.7% and a morbidity rate of 6%, and angiographic outcome was also good, with a complete occlusion rate of 75% at 6 months. The study was well-designed and well-conducted. The results are consistent with the results of other studies of the Surpass flow diverter. The Surpass flow diverter is a safe and effective treatment for intracranial aneurysms.

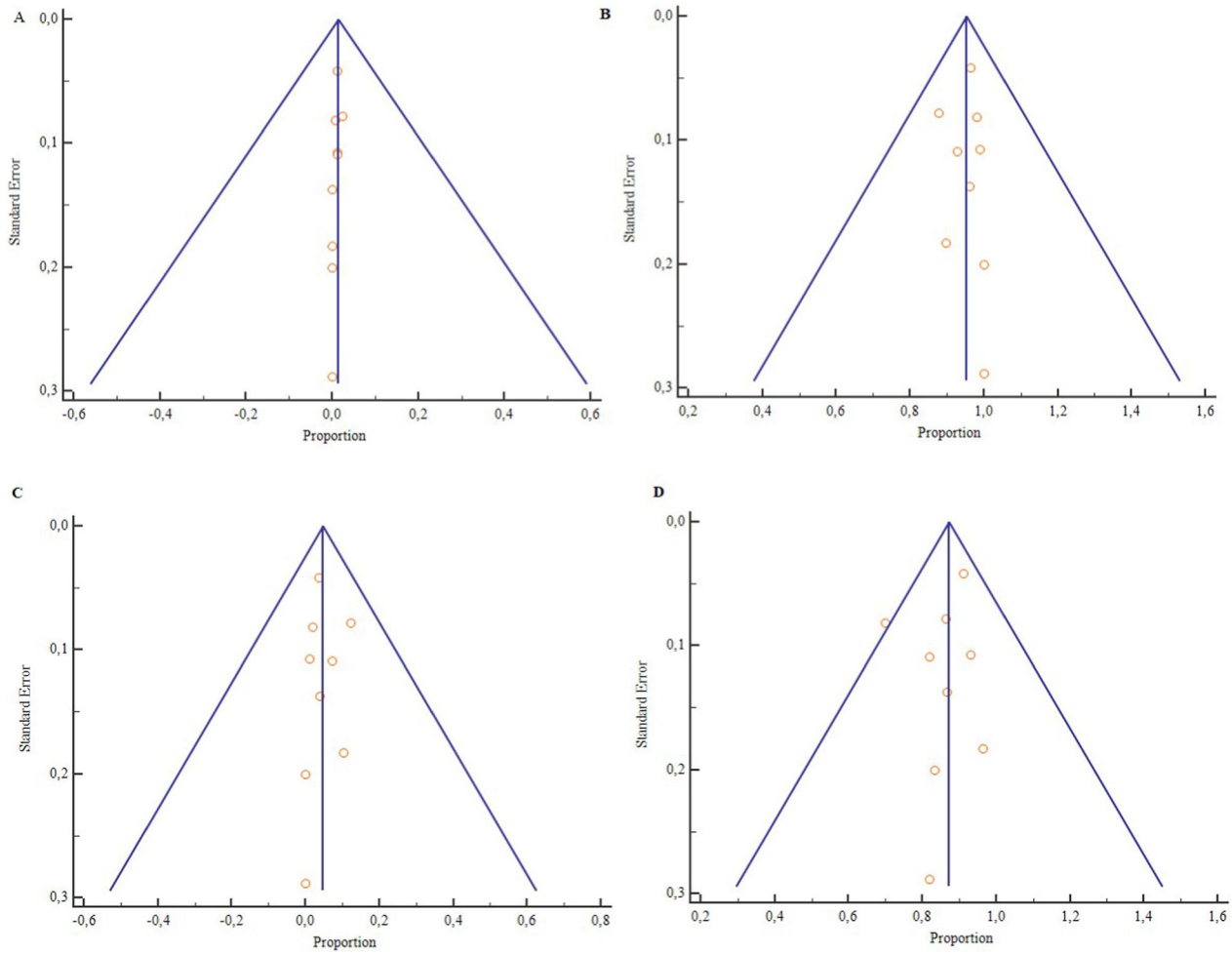

Fig. 3 Funnel plot assessing the risk of publication bias in outcomes: **A** Mortality, **B** Good outcome, **C** Poor outcome, **D** Complete or near complete occlusion. Publication biases are evident

The Surpass flow diverter is a new treatment for posterior circulation aneurysms. It is a small, mesh-like device that is inserted into the aneurysm to redirect blood flow and prevent rupture. The study by Taschner et al. [11] is the first prospective, multicenter study of the Surpass flow diverter for the treatment of posterior circulation aneurysms. The study included 53 patients with aneurysms that were not amenable to surgical clipping or coil embolization.

The results of the study showed that the Surpass flow diverter was a safe and effective treatment for posterior circulation aneurysms. The technical success rate was 98%, and the angiographic occlusion rate at 6 months was 75%. There were no deaths related to the procedure. The most common adverse events were intracranial hemorrhage (22%), headache (19%), and hearing loss (15%) [11].

Mahajan et al. [12] conducted an observational study in Medanta Institute of Neurosciences, Gurgaon, Haryana, India, and published in World Neurosurgery of the Surpass flow diverter for the treatment of ruptured intracranial aneurysms. The study included 16 patients with aneurysms that had ruptured within the past 72 h. The technical success rate was 100%, and the angiographic occlusion rate at 6 months was 87%. There were no deaths related to the procedure. The most common adverse events were vasospasm (37%) and coil migration (12%) [12].

Overall, the results of the study suggest that the Surpass flow diverter is a safe and effective treatment for ruptured intracranial aneurysms. It is a promising new option for patients with aneurysms that have ruptured within the past 72 hours [12].

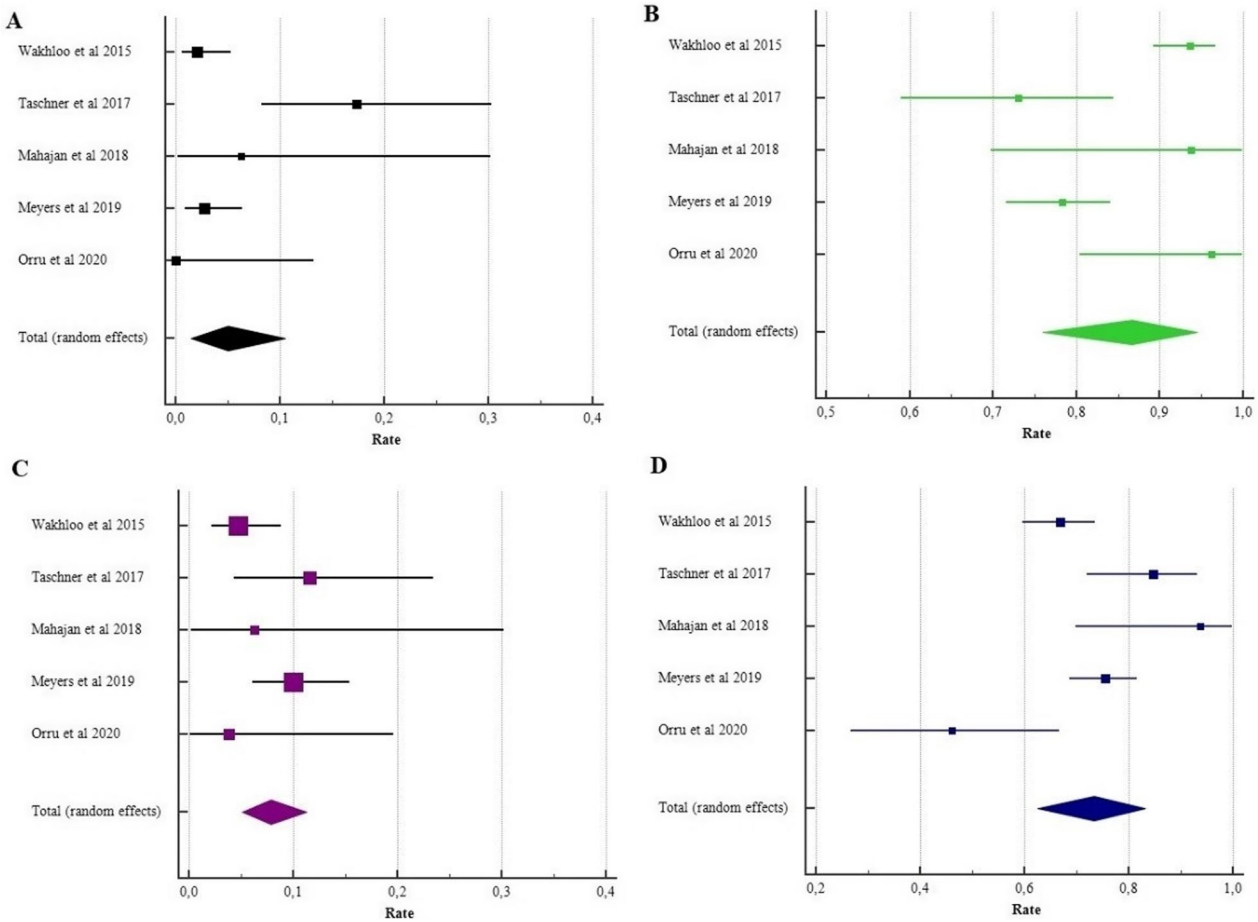

Fig. 4 Forest plot of pooled rate for outcomes Surpass device treatment: **A** Mortality, **B** Good neurological outcomes, **C** Poor neurological outcomes, **D** Complete or near complete. A random-effects model was applied

The SCENT trial [13] was a prospective, randomized controlled trial that compared the Surpass flow diverter to coil embolization for the treatment of unruptured intracranial aneurysms. The study included 180 patients with aneurysms that were at least 5 mm in diameter [13]. The results of the study showed that the Surpass flow diverter was not superior to coil embolization in terms of the primary endpoint, which was the rate of angiographic occlusion at 12 months. The technical success rate was 95% for both groups, and the angiographic occlusion rate was 62.8% for the Surpass flow diverter group and 69.9% for the coil embolization group [13].

However, the Surpass flow diverter group had a lower rate of major ipsilateral stroke or neurological death at 12 months (8.3 vs. 13.4%). This suggests that the Surpass flow diverter may be a safer option for patients with unruptured intracranial aneurysms.

Orru et al. [14] included anterior and posterior circulation aneurysms, wide-necked aneurysms, and giant aneurysm and concluded that his device is technically successful with a rate of 96%. The mean aneurysm occlusion rate at 6 months was 68%. There were no procedural-related deaths or strokes. The most common adverse events were transient neurological deficits (16%) and coil migration (8%). This device is safe and effective treatment for a variety of intracranial aneurysm [14].

Neuroendovascular treatment of intracranial aneurysms has progressed dramatically in recent decades. The high favorable outcome rate with a low complication rate makes endoluminal resolution using intracranial aneurysms an appropriate option for various types of aneurysms [15]. The development of flow diverters has contributed to the management of ruptured and non-ruptured aneurysms, being a safe technique, although not without complications. Through the reconstruction of parent artery and aneurysmal occlusion, they depend on changes in hemodynamic flow patterns. The induction of intra-aneurysmal thrombosis and the subsequent endothelization are fundamental mechanisms in the healing of the aneurysm. Our results demonstrate that

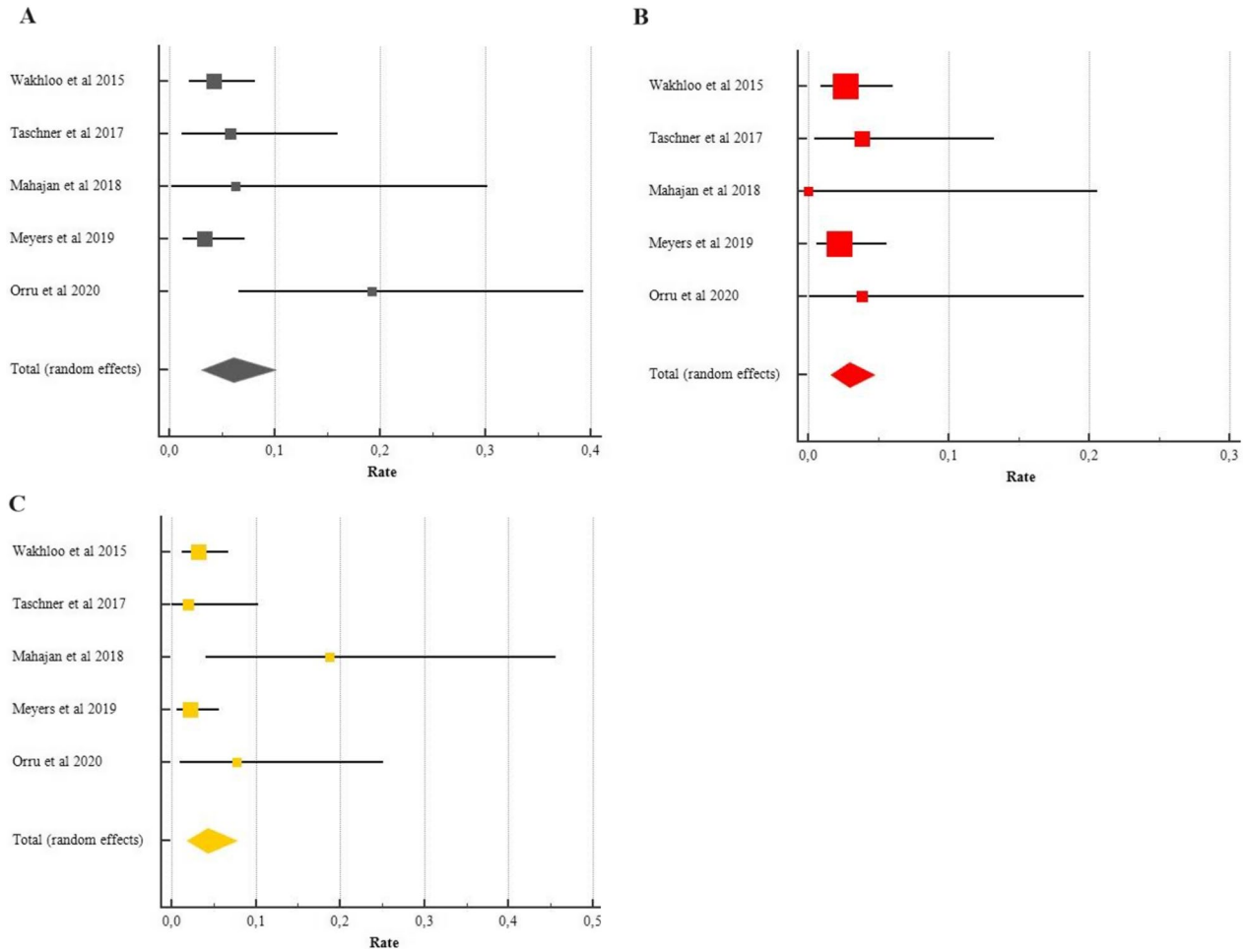

Fig. 5 Forest plot for the pooled rate of complications of treatment with Surpass device: **A** Thromboembolic complications, **B** Hemorrhagic complications, **C** Vasospasm

Surpass offers similar results to other flow diverters like PED and Silk.

After the deployment of the FD, ischemic and hemorrhagic complications, parent artery injury, side branch occlusion and related to the mechanical application of the device on the parent artery and aneurysm have been described [16]. Several studies have revealed asymptomatic ischemic after FD diverter treatment. Figures up to 8% have been reported for symptomatic thromboembolism in early stages after FD treatment [17, 18]. Brilstra et al. [19] report a rate of complications of 3.7% associated with coils embolization similar to that observed with the treatment of FD.

Hemorrhagic complications associated with giant aneurysms have been reported in the literature [20]. Rochaud et al. [21] report in a literature review that 50% of delayed hemorrhagic bleeding complications were associated with giant aneurysms. Ye et al., [22] report in a meta-analysis of mortality and mortality of 3.8% and 9.8%, respectively. The mortality associated with Surpass was similar to that observed with the PED rate [23]. One of the challenges in the context of after flow diverter treatment bleeding complications is the continuation or stopping of anticoagulant therapy [24].

Finally, the results presented in this study demonstrate the evidence in favor of Surpass flow diverter for the treatment of intracranial aneurysms.

Limitations

Our study has several limitations inherent in this class of research. Only three included studies were retrospective experiences, but with the possibility of selection bias. The publications included were all peer reviewed but there is a possibility of risk of publication bias. The limitation of accessing the original data may also be a cause of bias. Considering a low number of included studies, there may have been a reduction in the confidence and power of the study analysis.

Conclusion

Data from our meta-analysis suggests that Surpass flow diverter for treatment of intracranial aneurysms is associated with a high occlusion rate and low rate of complications. Further studies are necessary to confirm our results.

Abbreviations

CI	Confidence interval
FDs	Flow-diverting device
IA	Intracranial aneurysm
OR	Odds ratio
SAH	Subarachnoid hemorrhage

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s41984-023-00236-7.

Additional file 1. Newcastle - ottawa quality assessment scale case control studies.

Acknowledgements

Not applicable.

Author contributions

All the authors meet the authorship requirements, they all made substantial contributions to conception of the manuscript regarding the contribution to conception and design, acquisition of data and the correspondent interpretation, drafting the article, and making the critically revision of the intellectual content.

Funding

There was no funding.

Availability of data and materials

The datasets analyzed during the current study are derived from publicly available sources and can be accessed by contacting the respective data repositories or organizations. The specific sources and datasets utilized, along with the corresponding references, are listed in the reference section of this article. Additional details regarding the inclusion and exclusion criteria, search strategies, and statistical methods employed in the systematic review and meta-analysis can be obtained upon request from the corresponding author.

Declarations

Ethics approval and consent to participate

The present manuscript has not been submitted to other journal for simultaneous consideration. The manuscript has not been published previously and is not split up in other parts, no data have been manipulated or fabricated, and no information is presented as if were from the authors.

Consent for publication

Valid informed written consent of the guardian was taken to publish this letter to the editor. They were informed that the details of patient will not be disclosed.

Competing interests

The authors declare that they have no competing interests.

Received: 29 June 2023 Accepted: 19 August 2023
Published online: 02 November 2023

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