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Original Article

Sufficient versus deficient rims during percutaneous closure of ostium secundum type atrial septal defect: A systematic review and meta-analysis

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ABSTRACT

Background: The aim of this meta-analysis was to compare the efficacy and adverse events of percutaneous occlusion among patients with sufficient and deficient rims.
Methods: A systematic review of all articles published in the Pubmed, MEDLINE and Google Scholar databases was performed. Odds ratio (OR) and 95% CI were used as a measure of effect of the combination of studies. I^2 with 95% CI was estimated to assess study heterogeneity. For the meta-analysis, a random effects model was used.
Results: The systematic search identified ten studies which included 4355 patients; 2661 of those had sufficient rim and the remaining 1694 patients showed some rim deficiency. Implant failure rate was 4.13% CI 95% 3.53–4.72%. Compared to frequency of failures in the group with a deficient rim (5.43% CI 95% 4.35–6.50%), implant failure in patients with a sufficient rim was significantly lower (3.30% CI 95% 2.62–3.97%), OR 2.27 CI 1.34–3.83 (p 0.002).
The combined adverse events were 5.19% CI 95% 4.22–6.35% vs 2.7% CI 95% 2.08–3.31% in the deficient vs sufficient rim groups respectively (OR 2.21 CI 0.93–5.29; p 0.07). Implant failures and adverse events were more frequent in patients with posterior inferior rim deficiency.
Conclusion: Patients presenting a posteroinferior rim deficiency are associated to both, an increased incidence of closure failure and a combined adverse events occurrence. More studies on posterior rim deficiency are necessary to ensure the feasibility and safety of the percutaneous approach.

1. Introduction

Percutaneous closure of the secundum type atrial septal defect (ASD) is the treatment of choice and is primarily based on anatomical characteristics. Sufficient rims (more than 5 mm) are very important for a successful outcome and approximately 80% of cases meet the necessary requirements to be treated percutaneously.[1,2] Echocardiography in their different modalities (transthoracic, transesophageal or intracardiac) is crucial for monitoring and evaluation the margins of the defect during the procedure.

Aortic or anterosuperior rim deficit and device oversizing were associated with cardiac erosions at follow-up after device implantation.[3] However, percutaneous occlusion in cases with aortic rim deficiency is frequently performed and it is not an absolute contraindication for closure.[1,2] Recently, new percutaneous alternatives for closure have been reported in other types of interatrial defects.[4] Equivocal outcomes have also been reported regarding the efficacy of defect closure in cases with deficit in other rims, such as the posterior or posteroinferior rims.[5–7]

So far, no previous article has comprehensively summarized these data and estimated the pooled effect size. The present study aimed to conduct a meta-analysis to seek whether a deficient rim is associated with efficacy and adverse events in short and intermediate-term follow-up.

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2. Material and methods

2.1. Search strategy

The preferred reporting items for systematic review and meta-analysis (PRISMA) guidelines was followed in the present study. A systematic search was completed by two authors (FL and AC) in Pubmed, MEDLINE and Google Scholar. The following keywords were used: "deficient rim" (AND) "atrial septal defect". There were no similar systematic reviews in the Cochrane Library as of March 2022. The search was not limited by language or publication date.

2.2. Eligibility criteria

To select the studies, the following criteria was considered: 1) analytical studies (prospective or retrospective); 2) the objective was to compare a population with sufficient rim versus deficient rim; 3) no limitations on the population age; 4) rims evaluated with some echocardiogram modality (transthoracic, transesophageal or intracardiac); and 5) report efficacy and adverse events during the follow-up. Studies with insufficient data, duplicate studies, and certain types of publications (letters to the editor, editorials, and case reports) were excluded.

Two investigators (AC and FL) independently reviewed the titles and abstracts of the studies. Discrepancies between the selected articles among the authors were solved by consensus or opinion of a third investigator.

2.3. Data extraction and risk of bias assessment

The two authors independently extracted data. The risk of bias was assessed using the Newcastle–Otawa Scale (NOS). The NOS includes three domains, such as selection (point from 0 to 5 for cross-sectional studies and from 0 to 4 for others), comparability (point from 0 to 2), and exposure/outcome (point from 0 to 3). Then, studies were tiered according to the total scores to the following categories: very high (0–3 points), high (4–6 points), and low risk of bias (7–10 points).[8]

2.4. Statistical analysis

The primary outcome of the present study was the pooled implant failure and adverse events. Among adverse events, device migration, cardiac arrhythmias, cardiac perforation or erosion, cardiac tamponade or pericardial effusion, need for emergency surgery and death were included.

The meta-analysis was conducted with a statistical analysis performed with the Review Manager software 5.4 and SPSS 24. Categorical variables were expressed as a percentage and 95% CI. Continuous variables were expressed as mean and standard deviation. Categorical variables were compared with Chi square or Fisher's test and continuous variables with Student's t-test. The odds ratio (OR) and 95% CI were utilized as a measure of the effect of the combination of studies. I^2 with 95% CI was estimated to assess study heterogeneity. For the meta-analysis, a random effects model was used. A p value $\leq$ 0.05 was considered statistically significant. The presence of possible publication bias was not evaluated due to the small number of the included studies.

3. Results

3.1. Study selection

The study flowchart is presented in Fig. 1. After the title and abstract screening for 321 publications, 19 articles were selected for full-text assessment based on the predefined inclusion and exclusion criteria. Ultimately, ten observational studies were eligible for inclusion in the systematic review and meta-analysis.[5–7,9–15]

3.2. Study characteristics

The main characteristics of the included studies are summarized in Table 1. Ten studies with 4355 patients were selected: 2661 patients had sufficient rims and 1694 patients had some rim deficiency. Individually, four studies included patients with aortic rim deficit only, two studies with posteroinferior deficit only, and four studies with deficit of different types of rims. Of these last 4 studies, in 2 of them the posteroinferior rim deficit group had less than 5 patients.

Only one study reported events 24 h after implantation and the remaining 9 studies included a follow-up time of 20.9 ± 12.7 months. There were no significant differences between the clinical and procedural characteristics of patients grouped according to rim type (Table 2). All studies were cross-sectional.

In the study by Kijima et al[10] no complications could be identified in the group with posterior rim deficit and in the study by Cao et al[9] the outcomes were generally assessed; however, it was not included in the subgroup analysis because it was not possible to differentiate events in particular groups.

Eight studies used transesophageal echocardiography (TEE) for echocardiographic monitoring and the remaining 2 studies utilized transthoracic echocardiography (TTE). The rims were defined in 4–7 areas according to different definitions.[16–19] The location of the aortic rim was unanimous. The posteroinferior rim was defined in 2 studies by TEE, in 2 studies by TTE, and one by both methods. Eight studies defined sufficient rim as those with a length equal or larger than 5 mm, although two studies used a different definition (3–4 mm).

3.3. Risk of bias assessment

Based on the NOS, the total quality score of the individual articles varied from 4 to 9 points. Therefore, eight studies were categorized as "high risk" and only two studies as "low risk". Incomplete control of confounding variables existed in most of the included studies just as the sample size is not justified and it is not possible to compare the characteristics of the non-responders (Table 3).

3.4. Implant failure and adverse events

Implant failure was 4.13% CI 95% 3.53–4.72% (180/4355). The frequency of failures in the group with deficient rim (5.43% CI 95% 4.35–6.50%) was higher than in the group with sufficient rim (3.30% CI 95% 2.62–3.97%) OR 2.27 CI 1.34–3.83 (p 0.002) (Fig. 2).

Seven studies (including 2784 patients) evaluated the efficacy of percutaneous closure comparing aortic rim deficit. Implant failure was 4.51% CI 95% 3.38–5.63% in the deficient aortic rim group vs 3.58% CI 95% 2.63–4.52% in the sufficient rim group (OR 1.41 CI 0.96–2.09; p 0.08) (Figure A1). Five studies (gathering 1381 patients) included patients with posteroinferior rim deficiency compared with sufficient rim. The prevalence of failures in patients with deficient posteroinferior rim was 10.3% CI 95% 6.10–14.49% vs 2.1% CI 95% 1.28–2.91% compared with the group with adequate margins (OR 8.60 CI 1.84–40.18; p 0.006) (Figure A2).

The combined adverse events were 5.19% CI 95% 4.22–6.35% vs 2.7% CI 95% 2.08–3.31% in the deficient vs sufficient rim groups respectively (OR 2.21 CI 0.93–5.29; p 0.07) evaluating the 10 selected studies (Fig. 2). There were no differences compared with the aortic rim deficit 3.11% CI 95% 2.03–4.18% vs 3.66% 2.68–4.63%

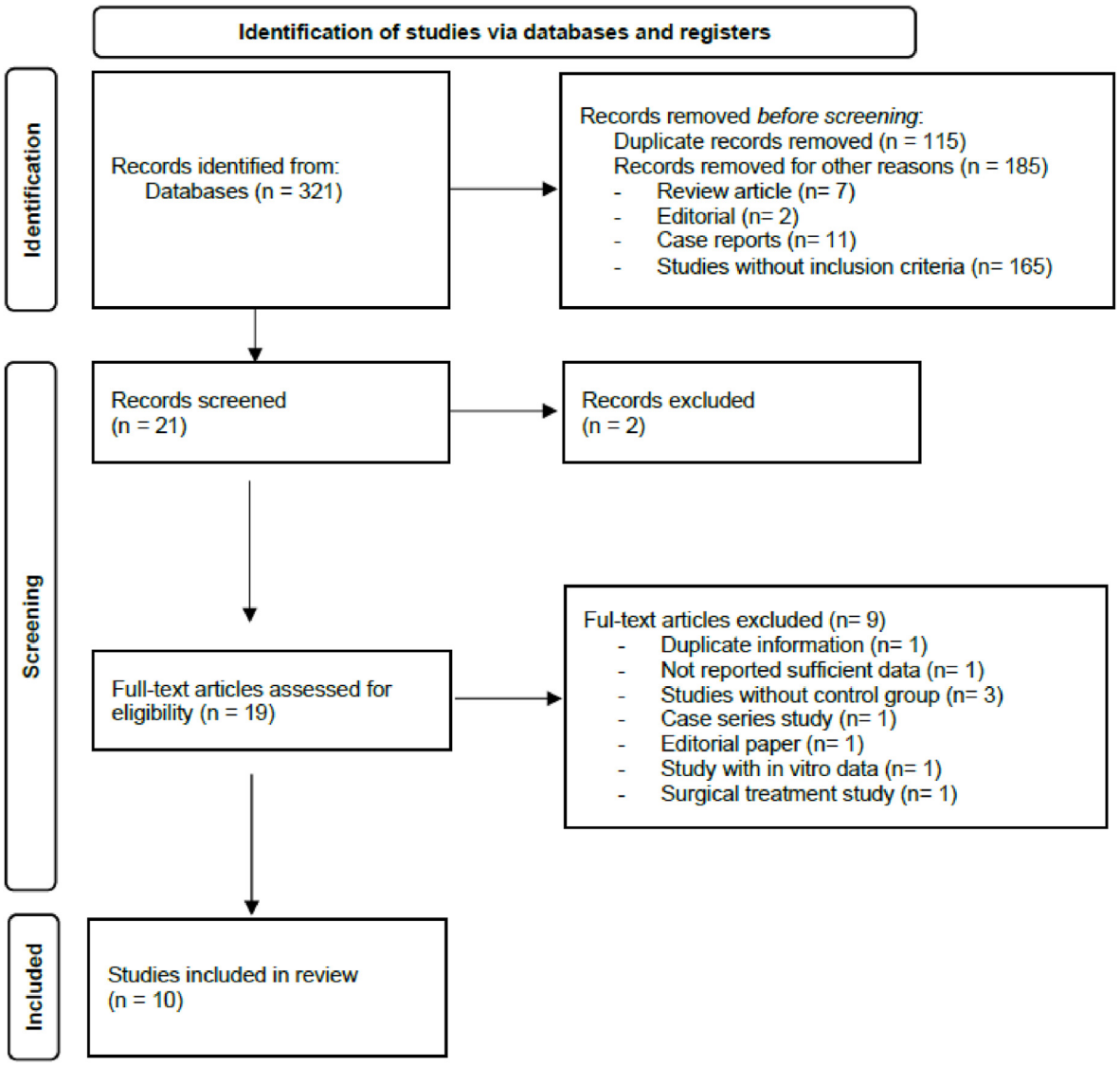

Fig. 1. Flow chart showing search results and selection of the studies included in the meta-analysis.

(OR 0.73 CI 0.46–1.17; p 0.19) (Figure A1). Posteroinferior rim deficit was associated with an increased in adverse events rate 4.81% CI 95% 1.74–7.87% vs 0.18% CI 95% 0–4.33% (OR 16.79 CI 1.01–278.01; p 0.05) (Figure A2). Arrhythmias and device migration were the two most frequent adverse events among the deficient rim group (Table 4).

The heterogeneity of the studies was intermediate in implant failure (I^2 37%) and high in adverse events (I^2 73%). There were differences in the heterogeneity of the subgroups. The studies were homogeneous with aortic rim deficiency (implant failure I^2 0% and adverse events I^2 0%) and significantly heterogeneous in the posteroinferior rim deficient subgroup (implant failure I^2 53% and adverse events I^2 70%).

3.4.1. Sensitivity analysis

None of the study individually significantly influence the overall estimate of the rate of implant failure or adverse events in the aortic rim deficiency group (Table 5). In presence of posteroinferior rim deficit, no study influences the outcome in cases of implant failure, however significant changes are observed in the pooled analysis of adverse events when excluding individual studies (Table 6).

3.5. Multiple rim deficiency

Kijima et al included 35 patients with deficits of more than one rim. Most of these with aortic rim deficit and posteroinferior rim deficit. The success rate of this group was significantly lower (86%) than patients with sufficient rims (100%) or only one rim deficit (98%).[10]

Amedro et al included 18 patients with posterior inferior rim deficit. Five of these also had a deficit of another rim. Four of them had adverse events.[6]

Cao et al included 46 cases with multiple border deficits but the efficacy and adverse events were not compared in these cases.[9]

4. Discussion

Currently, percutaneous closure is the treatment of choice for patient presenting ASD-OS even compared favorably with surgical

Table 1
Summary of studies included.

Author (publication year)	Number of patients	Group control (sufficient rim)	Group intervention (deficient rim)	Procedural guide/methods of measure	Definitions of deficient rim	Follow-up
Du Z et al (2002)	71	48 40 ± 24 years old	20 (Ao rim) 3 (PI rim) 21 ± 20 years old	TEE/ICE Balloon sizing	< 5 mm	6 months
Wang J et al (2004)	197	83	113 (Ao rim) 1 (PI rim)	TEE Balloon sizing	< 5 mm	24 months
Huang C et al (2007)	84	50 22.5 ± 18.8 years old	34 (Ao rim) 21.4 ± 22.3 years old	TEE Balloon sizing and maximum defect diameter	< 3 mm	21.6 ± 12 months
Li G et al (2012)	280	118 26.7 ± 17.8 years old	162 (Ao rim) 27.4 ± 17.2 years old	TTE Maximum defect diameter	< 4 mm	6 months
Kijima Y et al (2016)	474	101 45 ± 23 years old	338 (single defect, 323 Ao, 15 PI rim) 46 ± 22 years old 35 (multiple defects) 43 ± 22 years old	TEE/ICE Balloon sizing and maximum defect diameter	< 5 mm	25 ± 19 months
Cao C et al (2016)	507	355 48 (32–95) months old	152 (multiple types defects) 47 (31–86) months old	TTE N/A	< 5 mm	12 months
O´Byrne M et al (2016)	1564	911 7 (4–15) years old	653 (Ao rim) 5 (4–11) years old	N/A Balloon sizing and maximum defect diameter	< 5 mm	24 hours
Amedro P et al (2019)	241	191 N/A	32 (N/A) 18 (PI rim) 8 (1.4–85) years old	TEE Maximum defect diameter	< 5 mm	49 ± 10 months
Takaya Y et al (2020)	869	748 N/A	121 (PI rim) 49 (26–62) years old	TEE Maximum defect diameter	< 5 mm	24 months
Huang LL et al (2021)	136	91 27(2–74) years old	45 (PI rim) 14 (2–63) years old	TEE/TTE Maximum defect diameter	< 5 mm	14 (11–24) months

Aortic (Ao). Posteroinferior (PI). Transesophageal echocardiography (TEE). Transthoracic echocardiography (TTE). Intracardiac echocardiography (ICE).

Table 2
Baselines and procedural characteristics.

	All patients	Sufficient rim	Deficient rim	P value
Female; % (n)	63.8 (2077)	62.6 (1049)	65 (1028)	0.16
Age; Years (SD)	26.6 (14.5)	27.6 (16.1)	25.9 (14.5)	0.85
Defect size; mm (SD)	18.4 (4.6)	16.7 (3.5)	19.7 (5.1)	0.21
Device size; mm (SD)	23.9 (3.9)	21.3 (2.8)	25.5 (3.9)	0.16
Fluoroscopy time; min (SD)	11.9 (3.8)	10.9 (3.4)	12.8 (4.3)	0.47

intervention. Rim deficiency is the paramount importance when planning and performing the procedure and this meta-analysis shows that patients with sufficient rims have a lower prevalence of implant failures and are associated with fewer adverse events compared with patients showing a deficient rim. However, these results depend on the defective rim involved.

There is a greater experience approaching patients with aortic rim deficiency and in different series the frequency of this finding is high, ranging from 30% to 60% of cases.[20] The results of this meta-analysis are consistent with the current recommendations, stating that the deficit of the aortic rim does not represent a contraindication for percutaneous approach.[1,2] There were no differences regarding implant failure or occurrence of adverse events in patients with aortic rim deficiency compared to patients with sufficient rims.

Regarding the posteroinferior rim deficit, this meta-analysis shows that it is associated with an increase in implant failures, as well as adverse events during follow-up. Adverse events were mainly cardiac arrhythmias and device migration.

Deficiencies of the posteroinferior rim, or coronary sinus rims are rare and account for less than 5% of cases. Generally, they are considered a contraindication for percutaneous occlusion. When the occlusion of on ASD-OS with posteroinferior deficit rim is attempted, the rate of implant failure is high, mainly due to inadequate positioning of the device.[21] There were similar findings among other working groups and this could possibly explain the increase in device migration cases.[6]

Some authors report adequate outcomes when closing a defect with posterior inferior rim deficiency. Cao et al were successful treating patients with less than 5 mm rims using devices up to 6 mm larger than the maximum measured diameter, of note, during the procedure they monitoring the rims using a combination of TTE and TEE for a better understanding of the anatomy. It is possible that a more detailed and better evaluation of this rim will allow the correct selection of candidates for percutaneous occlusion.[9]

The complete absence of the posterior inferior rim (bald) has been described as a predictor of failure although, when this rim is deficient (less than 5 mm but greater than 0 mm) the probability of success increases.[7] The “bald” appearance of the posterior border is a finding that might support the diagnosis of sinus venosus type ASD.[22]

In cases with posteroinferior rim deficit, different measures can be useful for taking the decision of percutaneous treatment. If balloon sizing is performed, a notch of less than 2 mm could

Table 3
Detailed results of the risk of bias assessment of the included studies bases on the Newcastle–Ottawa Scale (NOS).

Study	Representativeness of the sample	Sample size	Nonrespondents	Ascertainment of the exposure	Comparability of subjects in different groups	Assessment of outcomes	Statistical test	Total score	Risk of Bias
Du et al	★			★★		★	★	5	High
Wang et al	★			★★		★	★	5	High
Huang et al	★			★★		★	★	5	High
Li et al	★			★★		★	★	5	High
O´Byrne et al	★	★	★	★★	★★	★	★	9	Low
Cao et al	★			★★		★	★	5	High
Kijima et al	★			★★		★	★	5	High
Amedro et al	★			★★		★		4	High
Takaya et al	★	★		★★	★	★	★	7	Low
Huang et al	★			★★		★	★	5	High

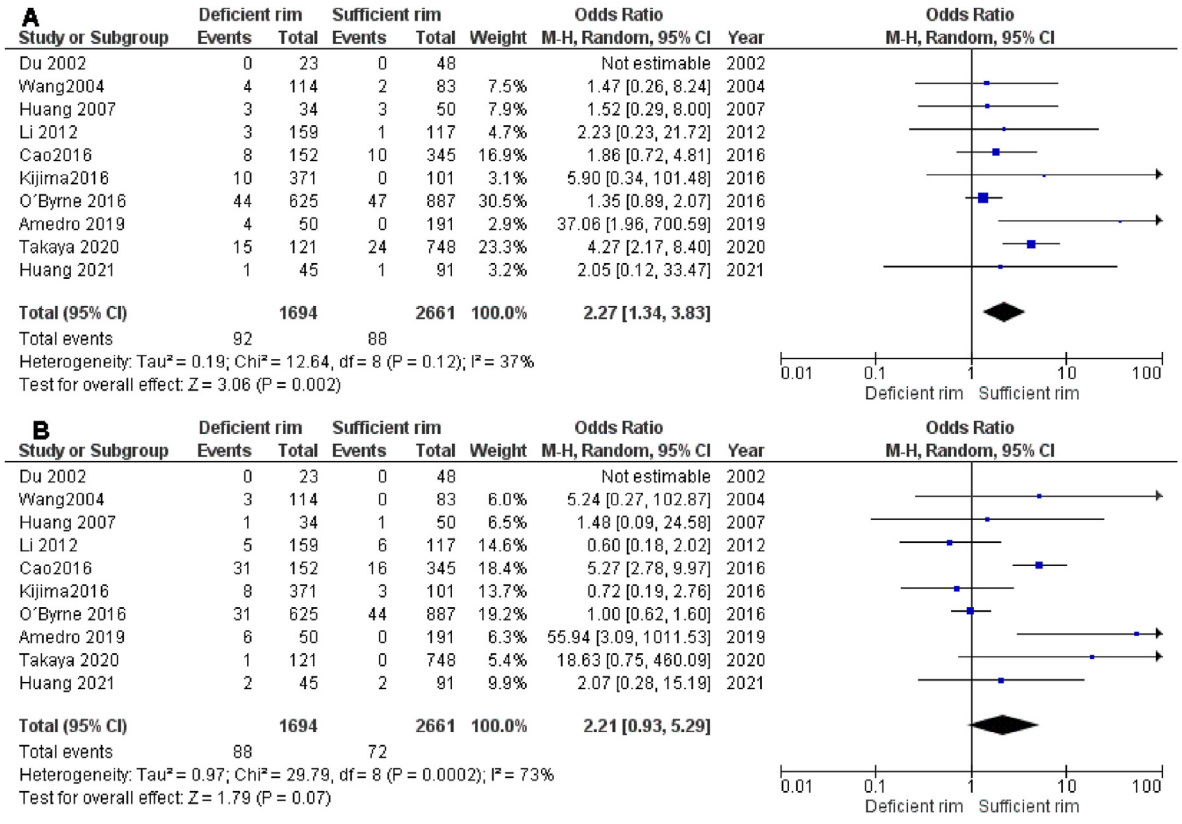

Fig. 2. Forest plot reflecting failure of implant (**A**) and follow-up adverse events after procedural closure (**B**) of ASD.

Table 4
Follow-up complications.

	Sufficient rim (n 2661)	Deficient rim (n 1694)	OR (CI 95%)
Device migration	0.56% (15)	1.23% (21)	2.21 (1.13–4.39)
Cardiac arrhythmias	1.80% (48)	3.18% (54)	1.79 (1.20–2.66)
Cardiac tamponade or pericardial effusion	0.11% (3)	0.17% (3)	1.57 (0.26–9.15)
Need for emergency surgery	0.22% (6)	0.59% (10)	2.62 (0.94–7.80)

Table 5
Aortic rim deficiency. Meta-analysis estimates, given named study is omitted.

	OR	CI 95%
Implant Failure		
Du 2002	1.41	0.96–2.09
Wang 2004	1.41	0.94–2.10
Huang 2007	1.41	0.94–2.10
Li 2012	1.39	0.94–2.07
Kijima 2016	1.39	0.94–2.06
O'Byrne 2016	1.78	0.66–4.82
Amedro 2019	1.41	0.96–2.09
Adverse events		
Du 2002	0.73	0.46–1.17
Wang 2004	0.70	0.44–1.12
Huang 2007	0.69	0.43–1.12
Li 2012	1.04	0.37–2.90
O'Byrne 2016	1.14	0.36–3.59
Amedro 2019	0.73	0.46–1.17

Table 6
Posterior rim deficiency. Meta-analysis estimates, given named study is omitted.

	OR	CI 95%
Implant Failure		
Du 2002	8.60	1.84–40.18
Kijima 2016	7.79	1.14–53.29
Amedro 2019	4.37	2.29–8.33
Takaya 2020	16.37	1.48–181.56
Huang 2021	14.90	1.75–127.80
Adverse events		
Du 2002	16.79	1.01–278.01
Amedro 2019	4.28	0.56–32.45
Takaya 2020	17.82	0.20–1590.02
Huang 2021	66.79	6.57–678.91

represent a contraindication to advance with the implant.[23] Higher failure rates have been reported with larger defects (30 mm) as well as with higher defect size/total septum length ratios.[24] A defect size/total septum length ratio ≤0.35, aortic rim/defect size ratio >0.75, and posterior inferior rim/defect size ratio >1.0 are TEE predictors of success that can be utilized in both children and adults.[25] An attractive alternative for safety of the implant in these cases is the use of a personalized 3D printed models to identify candidates for percutaneous occlusion.[26]

Rim deficiency was found to be associated with an increased incidence of device migration. It is mandatory to adjust the measurements (for example, balloon sizing) for a correct device choice. Additionally, about 25% of ASDs may have a floppy posteroinferior rim,[27] defined as movement of the border back and forth and flattering with blood flow. In general, a slight oversizing is allowed to avoid migration. The presence of large defects with a floppy posterior or posteroinferior rim may make percutaneous occlusion difficult.[28]

Regarding the higher incidence of arrhythmias in patients with rim deficit, this could be explained by the use of larger devices causing device/conduction tissue interaction.[29]

This study has limitations mainly it is based on retrospective studies with potential selection and adverse event reporting biases. The definitions of poor rim were not strictly the same and there may have occurred group overlap. There was heterogeneity among the studies, specifically in those evaluating posterior rim deficiency as well as publication bias. However, results in aortic rim deficit show little heterogeneity and consistent results.

Evaluation of the posteroinferior rim with TTE subcostal views is suggested to differentiate strict posterior from posteroinferior rim deficiency.[30] This was not consistent in the studies that evaluated the feasibility of treatment with posterior inferior rim deficit. Kijima and Takaya's works only evaluated rims with TEE.

In general, the studies that showed the feasibility of occlusion with posterior inferior rim deficit are unicentric, with very few reports of failures (they may be non-reproducible experiences), with a poorly represented pediatric population and lack of long-term follow-up.

5. Conclusion

Although patients with rim deficiency have an increased risk of failure during percutaneous closure and adverse events, in general, those patients can be treated safely and effectively by catheter intervention, especially when the deficient rim is the aortic. Patients presenting a posteroinferior rim deficiency are associated to both, an increased incidence of closure failure and a combined adverse events occurrence. More studies on posterior rim deficiency are necessary to ensure the feasibility and safety of the percutaneous approach.

What is already known

Percutaneous occlusion in cases of aortic rim deficiency is safe and effective and occlusion of ASDs with devices in defects with rim deficits other than the aortic rim is not recommended.

What this study adds

ASD with deficient posteroinferior rim was associated with less efficacy in occlusion and an increase in adverse events.

Declaration of competing interest

No author has conflicts of interest. The authors have not received financial support for the development of the research.

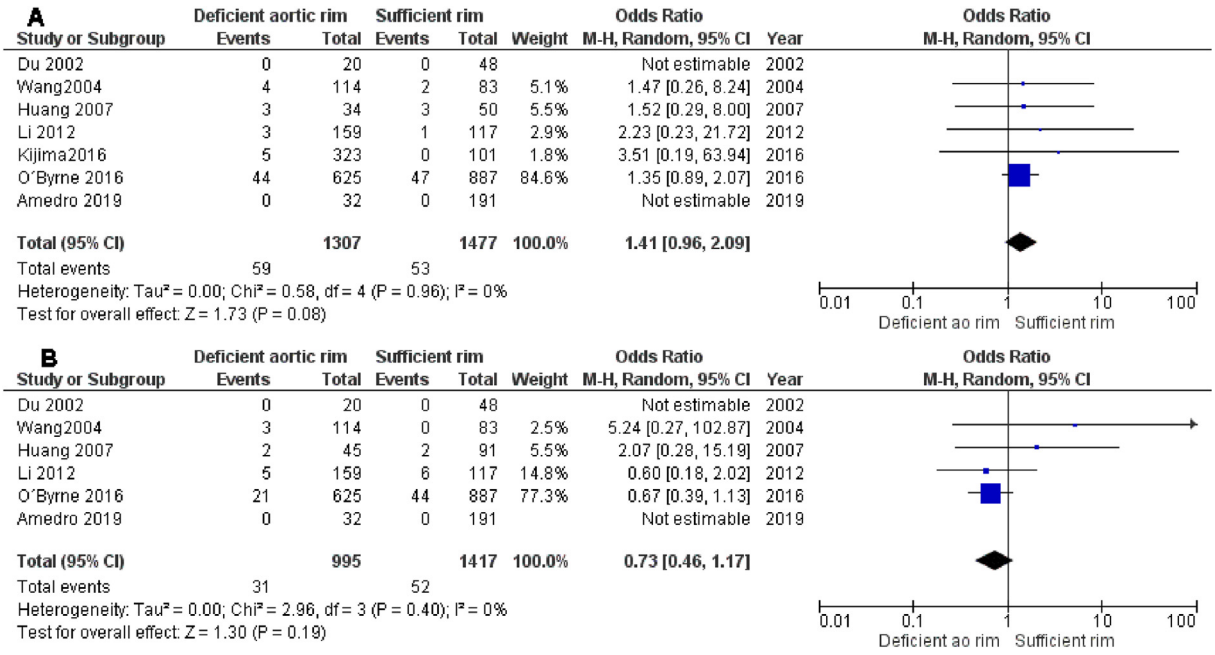

Fig. A1. Forest plot reflecting failure of implant (**A**) and follow-up adverse events after procedural closure (**B**) of ASD in aortic rim deficiency.

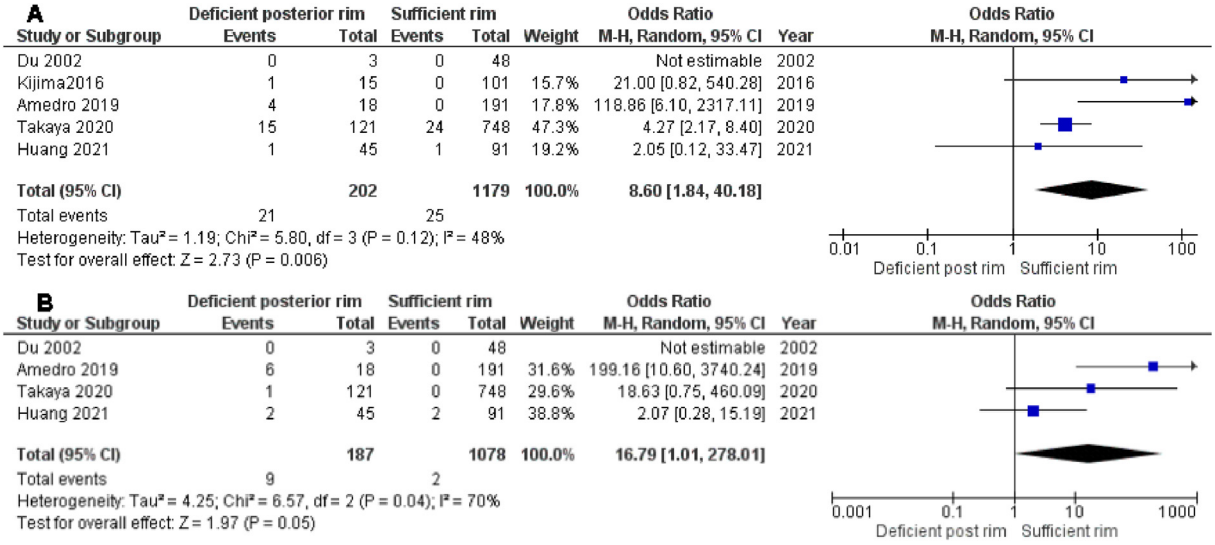

Fig. A2. Forest plot reflecting failure of implant (**A**) and follow-up adverse events after procedural closure (**B**) of ASD in posterior inferior rim deficiency.

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