
Transcatheter tricuspid valve repair for tricuspid regurgitation: a meta-analysis of MitraClip, TriClip, and PASCAL Systems

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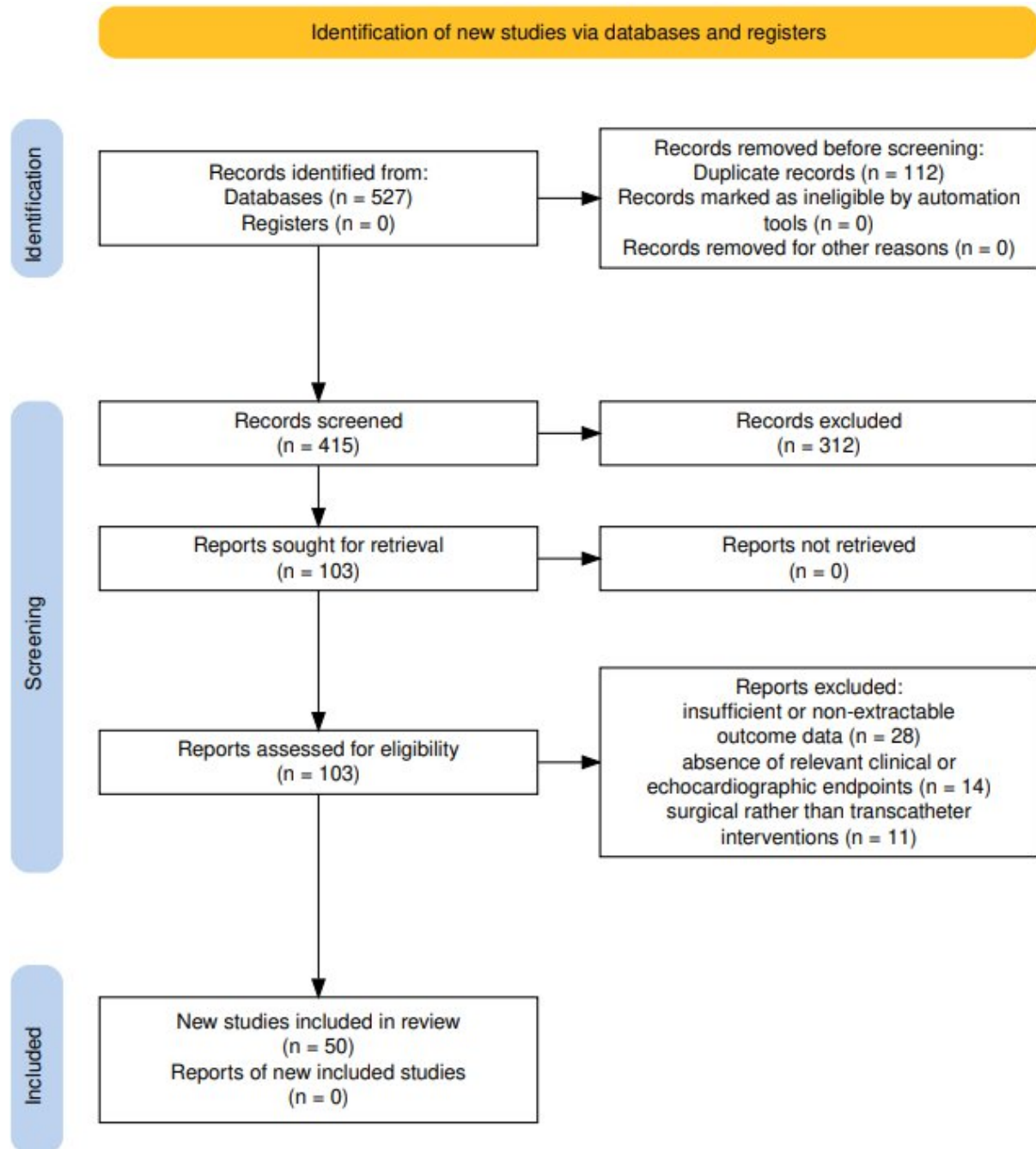
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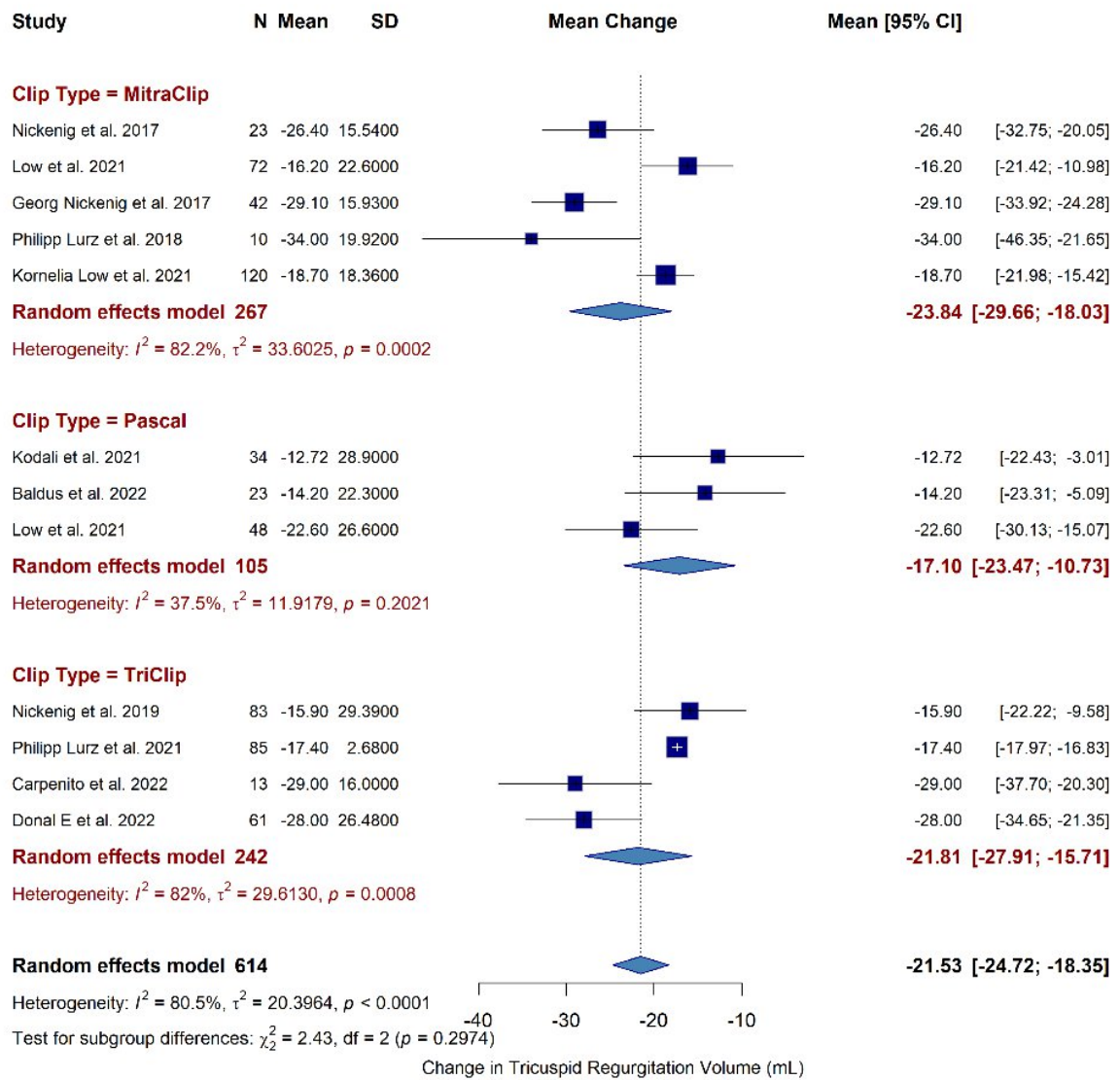
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Supplementary Material

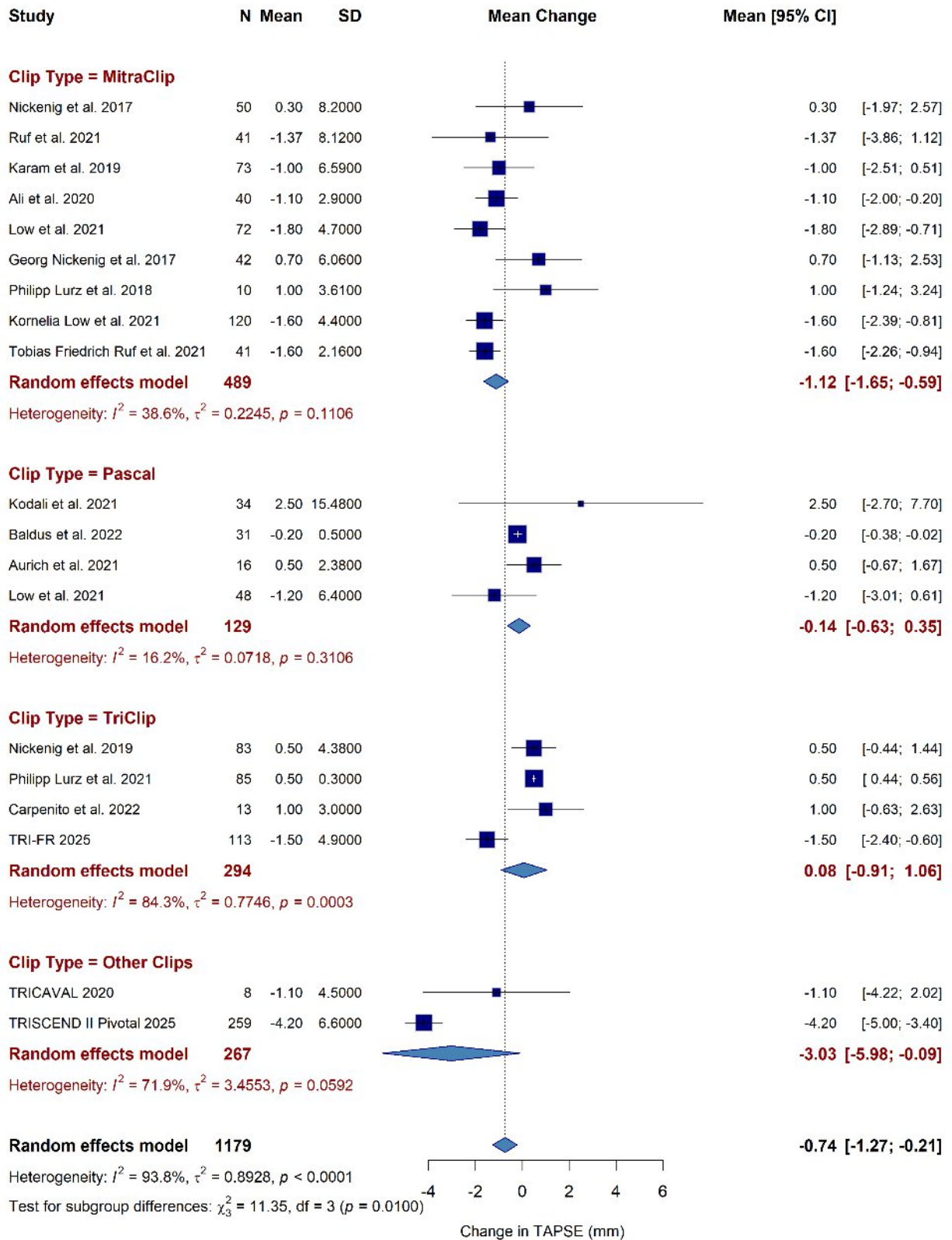
Supplementary Figure S1. Prisma flow diagram



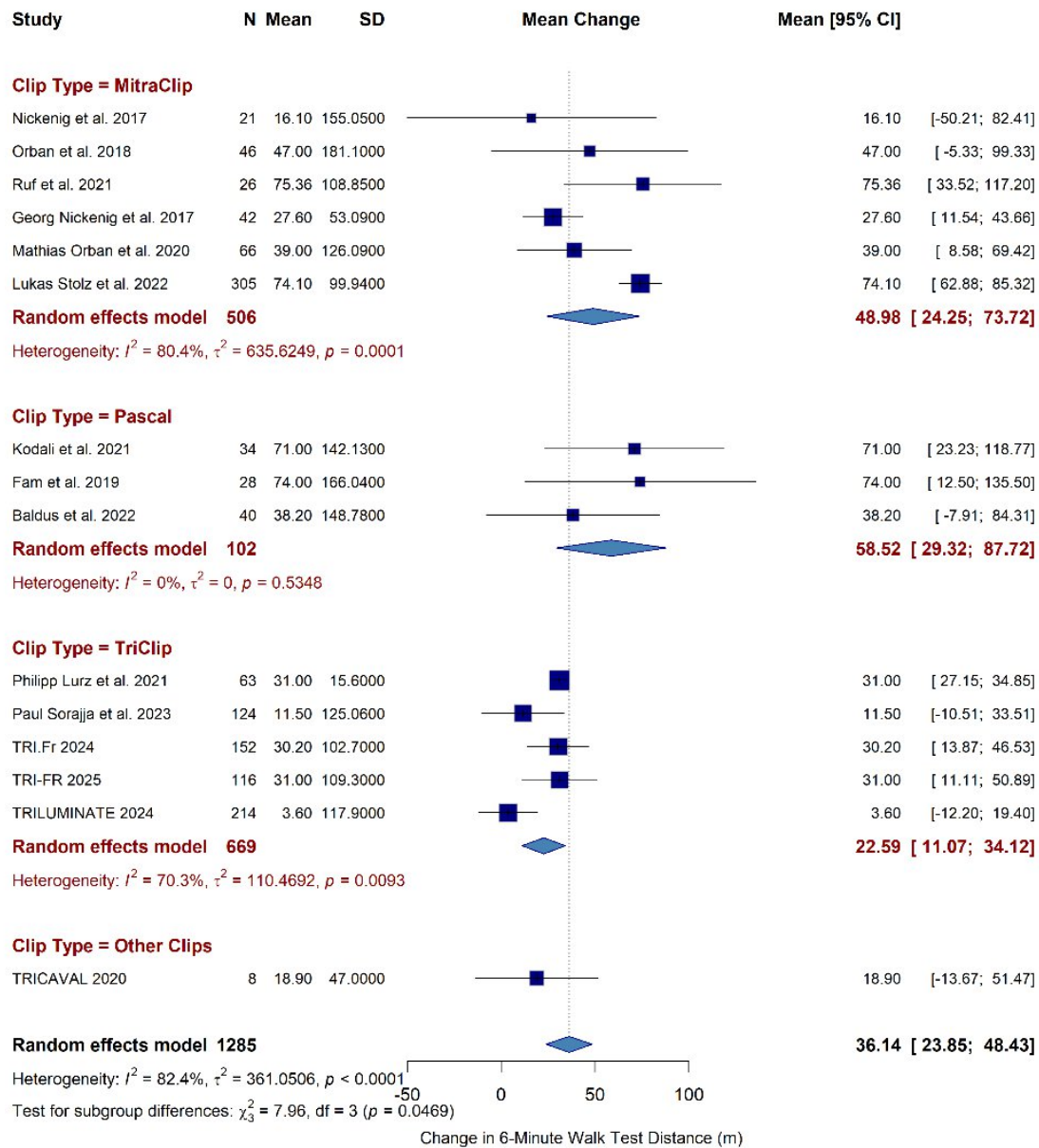
Supplementary Figure S2. Tricuspid Regurgitation Volume



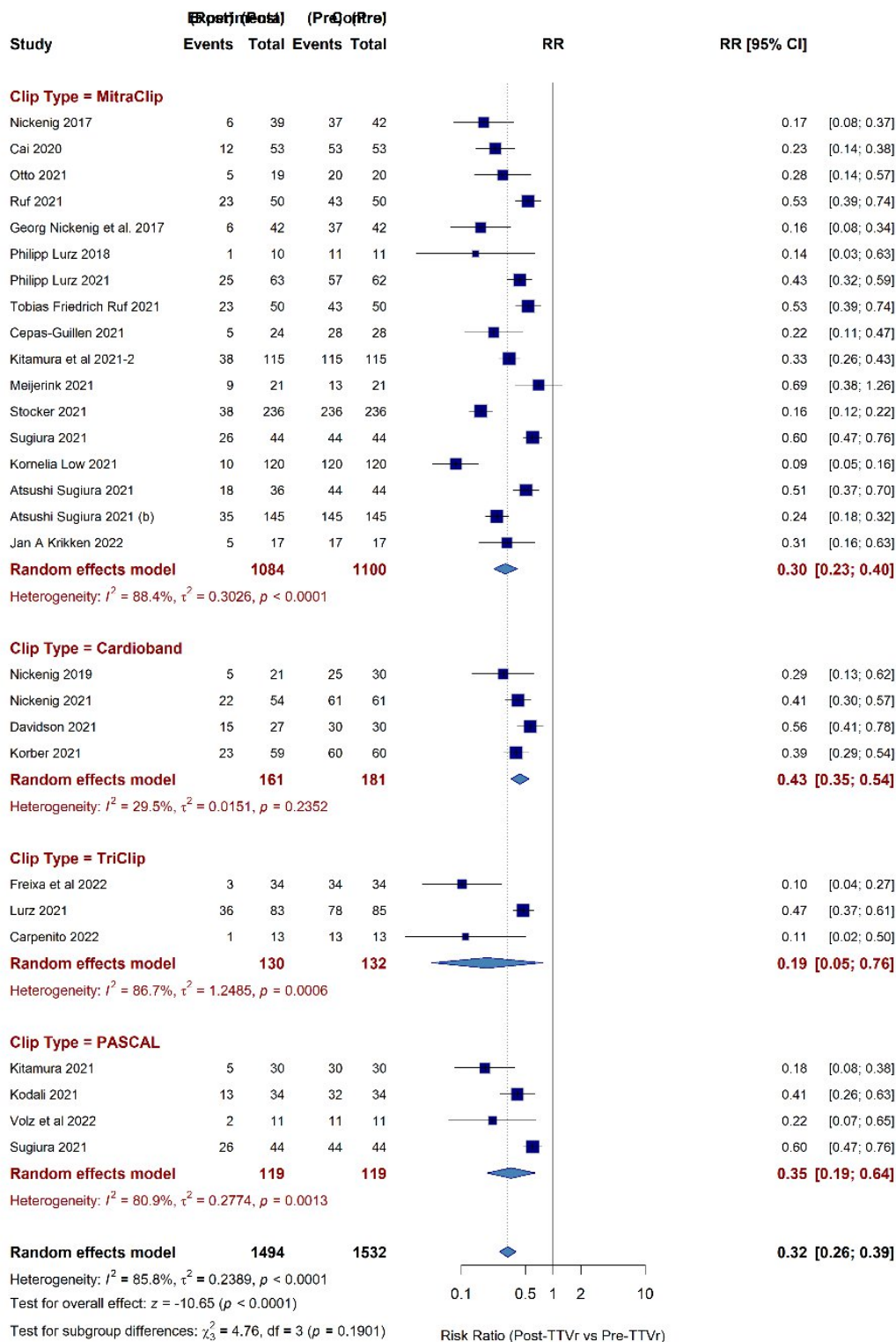
Supplementary Figure S3. TAPSE



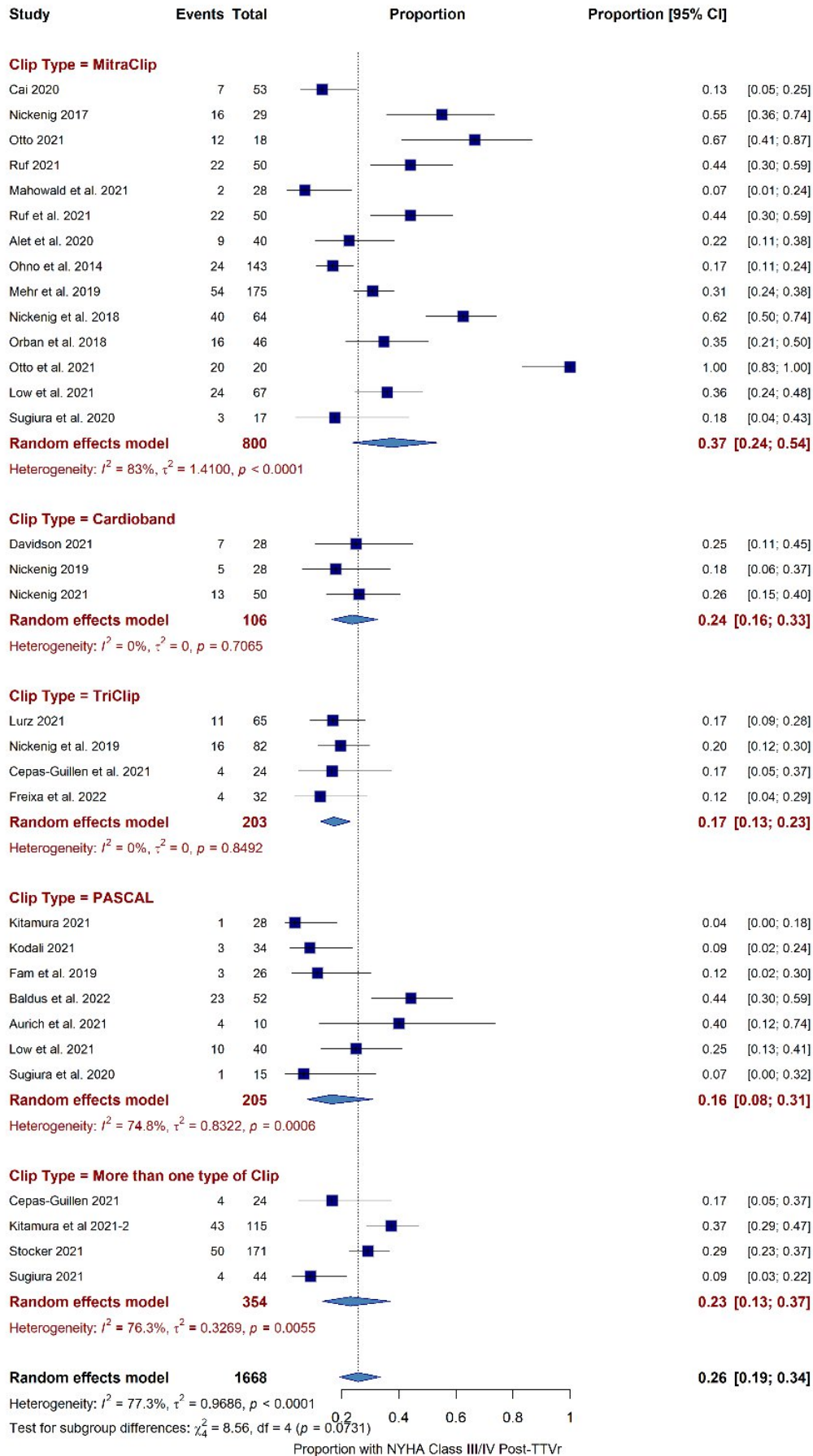
Supplementary Figure S4. 6 MWT



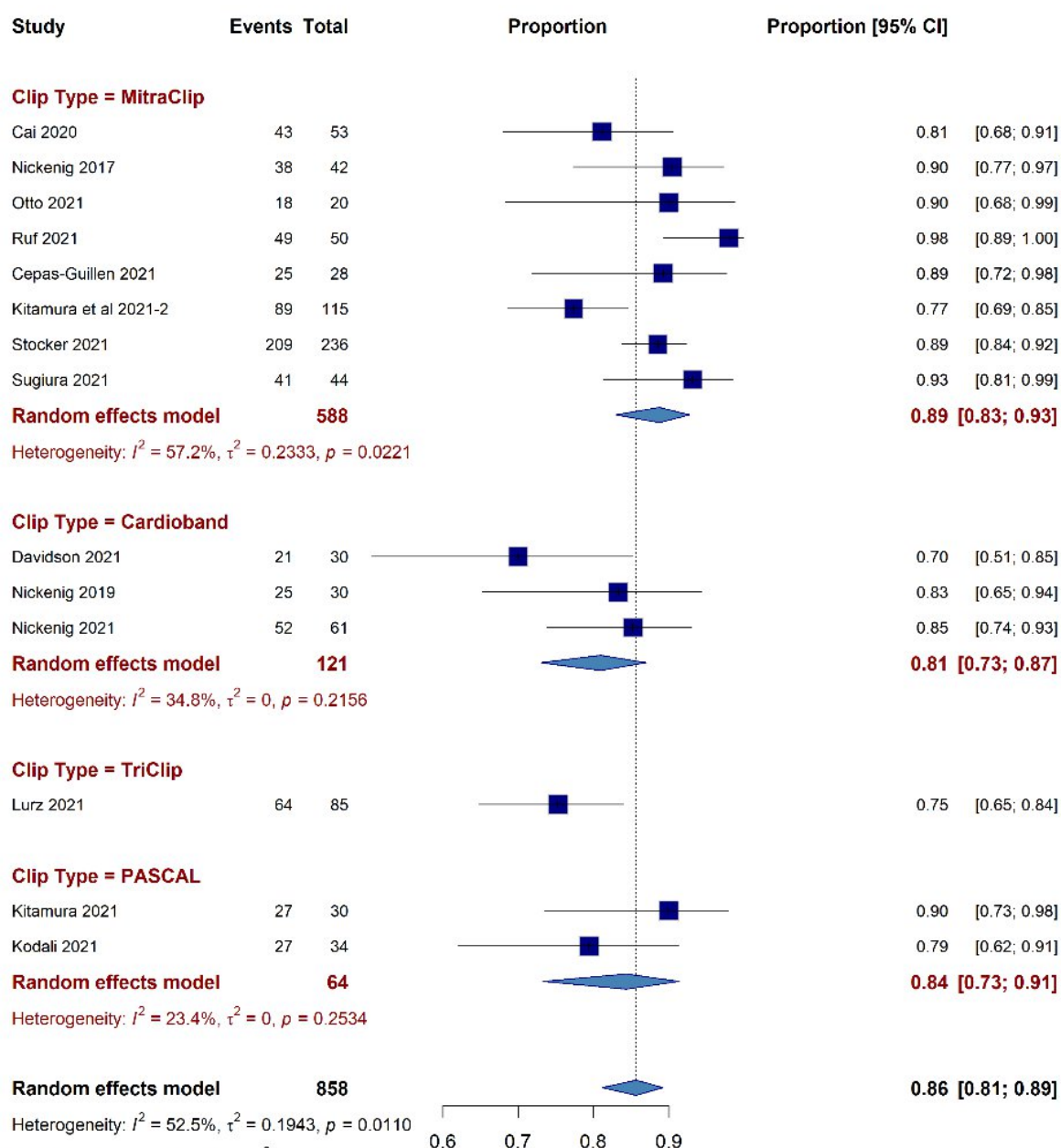
Supplementary Figure S5. TR Severity



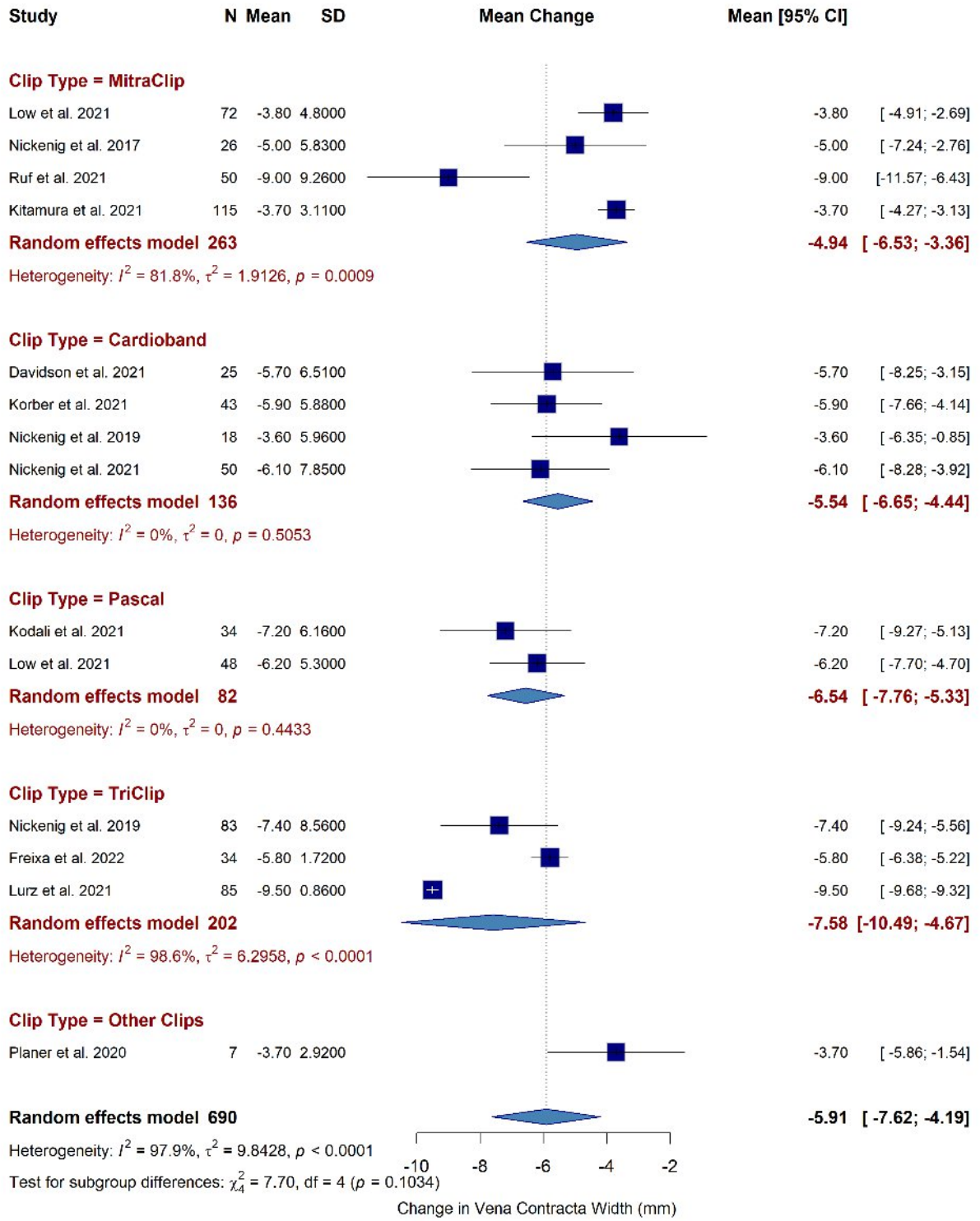
Supplementary Figure S6. Post treatment NYHA Class greater than 3



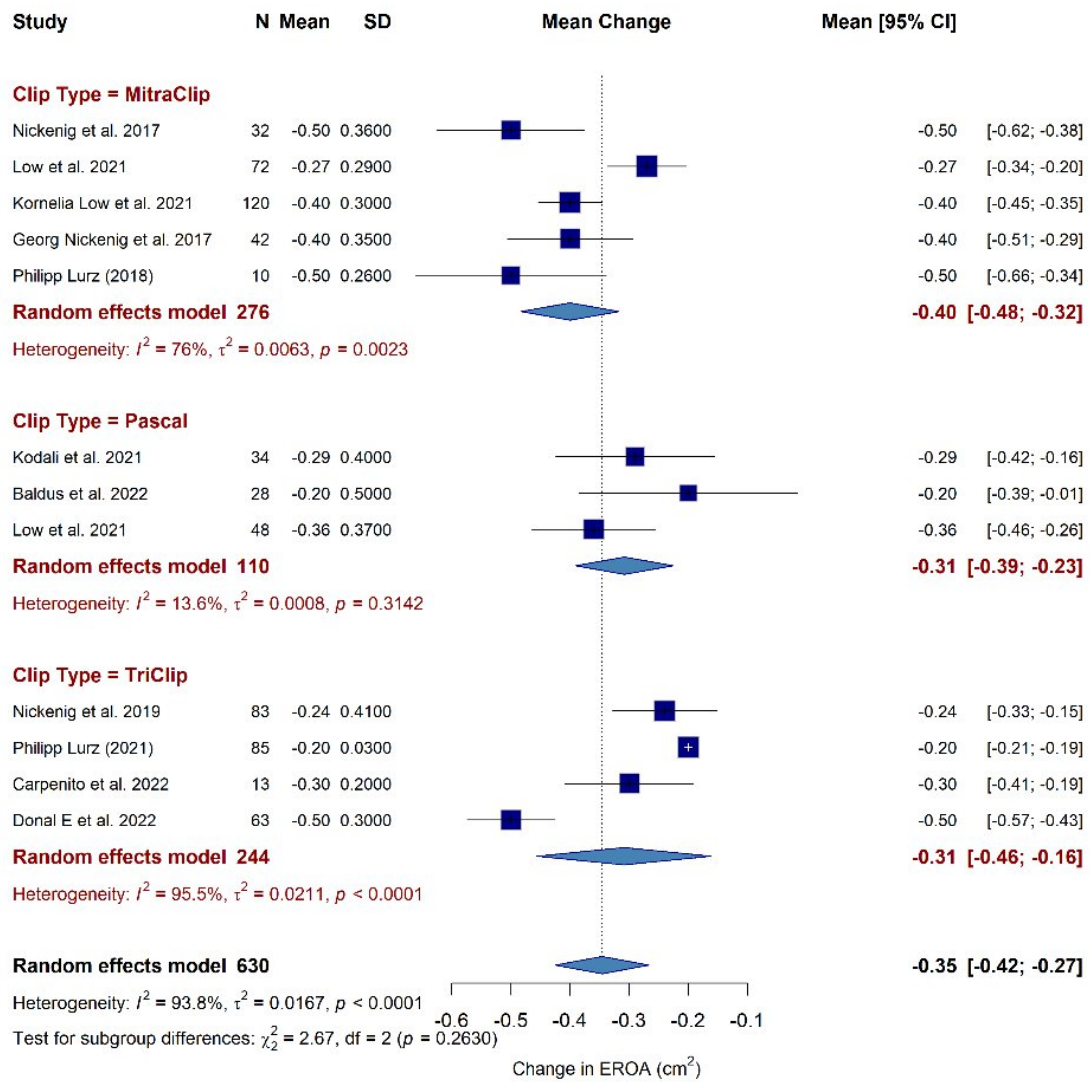
Supplementary Figure S7. Pre treatment NYHA Class greater than 3



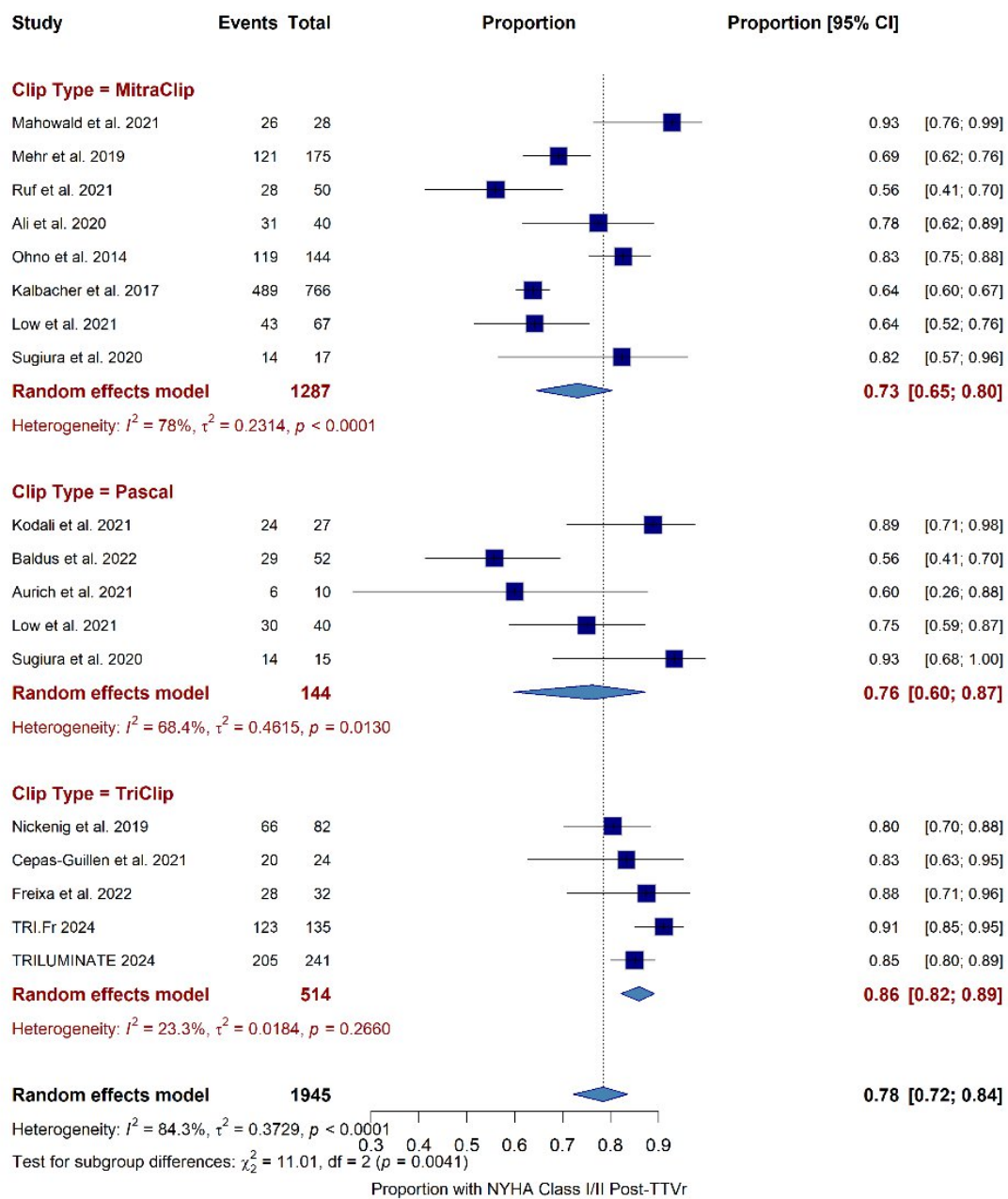
Supplementary Figure S8. Vena contracta width



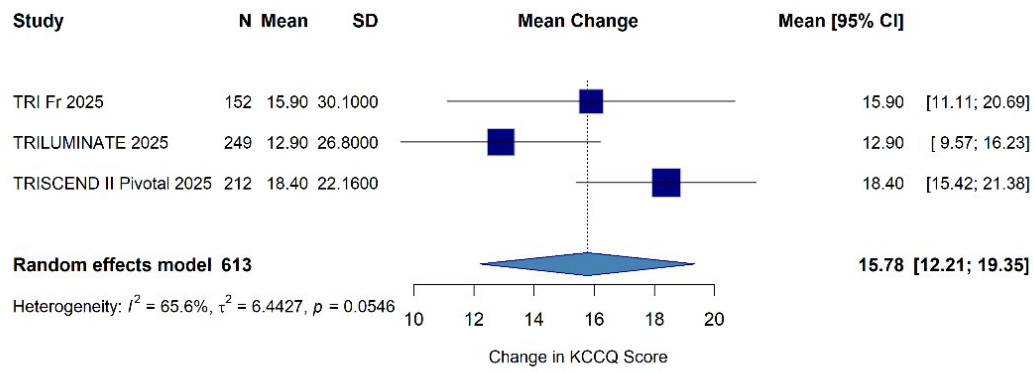
Supplementary Figure S9. EROA



Supplementary Figure S10. NYHA lesser than 3



Supplementary Figure S11. KCCQ



| Database | Search Strategy | Search Date | Search results |
|----------|-----------------|-------------|----------------|
|----------|-----------------|-------------|----------------|

| | | | |
|------------------|---|--------------|-----|
| PubMed/MEDLINE | ("Tricuspid Valve Insufficiency"[Mesh] OR "tricuspid regurgitation" OR "TR") AND ("Transcatheter Tricuspid Valve Repair" OR "TTVr" OR "transcatheter repair" OR "edge-to-edge repair" OR "TEER") AND ("MitraClip" OR "TriClip" OR "PASCAL") | 1 March 2026 | 191 |
| Embase | ('tricuspid regurgitation'/exp OR 'tricuspid regurgitation' OR 'tricuspid insufficiency') AND ('transcatheter tricuspid valve repair' OR 'transcatheter repair' OR 'edge to edge repair' OR 'TEER') AND ('mitraclip' OR 'tricleip' OR 'pascal') | 1 March 2026 | 124 |
| Cochrane Library | ("tricuspid regurgitation" OR "tricuspid insufficiency") AND ("transcatheter tricuspid valve repair" OR "edge-to-edge repair" OR "TEER") AND ("MitraClip" OR "TriClip" OR "PASCAL") | 1 March 2026 | 212 |
| Total | | | 527 |

Table S1. Search strategy

| Study (Author/Year) | Study Design | No. of Participants | Device(s) | Follow-up | Outcomes Assessed / Primary Endpoints |
|------------------------------|-------------------------------|---------------------|-------------------------------|----------------------|--|
| Carpeni et al., 2022 | Prospective, single-arm study | 13 | TriClip | 6 months | surgery, LVEF, TR severity grading |
| Lurz et al., 2021 | Prospective, single-arm study | 28 | TriClip | 30 days and 6 months | All-cause mortality, TR regurgitation |
| Low et al., 2021 | Retrospective analysis | 85 | MitraClip, PASCAL | 30 days | TAPSE, NYHA (grade III-IV), EROA, TR regurgitation volume, Tricuspid annulus diameter. |
| Krikken et al., 2022 | Retrospective analysis | 120 | MitraClip, TriClip | 30 days | TR severity grading, NYHA (grade III-IV). |
| Sorajja et al., 2023 | Prospective randomized trial | 17 | TriClip | 30 days and 1 year | post renal failure, Nonelective cardiac |
| Donal et al., 2022 | Prospective, single-arm study | 350 | TriClip device | NA | EROA, PISA radius, TR regurgitant volume. |
| Sugiura et al., 2021a | Retrospective analysis | 146 | MitraClip, TriClip, or PASCAL | 1 year | TR severity $\geq 3+$, All-cause mortality, TR severity grading. |
| Orban et al., 2020 | Observational study | 145 | MitraClip or PASCAL system | 1 year | 6 MWD, All-cause mortality, NYHA (grade III-IV), TR severity grading. |

| | | | | | |
|------------------------------|------------------------|-----|----------------------------|-------------------|---|
| Lurz et al., 2018 | Retrospective analysis | 119 | MitraClip | 30 days | 6 MWD, Procedural success, Tricuspid annulus diameter, LVEF, PISA, EROA, TR severity grading. |
| Stolz et al., 2022 | Retrospective analysis | 42 | MitraClip or PASCAL system | 1 year | All-cause mortality, Rehospitalization for heart failure, 6-MWD. |
| Ruf et al., 2021 | Retrospective analysis | 305 | MitraClip | 30 days | NYHA (grade III-IV), TAPSE, and TR severity grading. |
| Sugiura et al., 2021b | Retrospective analysis | 50 | Pascal, MitraClip | 30 days, 3 months | NYHA (grade III-IV), LVEF, TAPS |
| Nickenig et al., 2017 | Observational study | 80 | MitraClip | 30 days | mortality, MI, Stroke, New onset renal |
| Nickenig et al., 2017 | Observational | 42 | MitraClip NT | In-hospital | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Cai et al., 2020 | Observational | 53 | MitraClip NT | 14 mo | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Otto et al., 2021 | Observational | 20 | MitraClip NTR/XTR | 30-d | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Ruf et al., 2021 | Observational | 50 | MitraClip XTR | 30-d | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Kitamura et al., 2021 | Observational | 30 | PASCAL | 1-y | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Kodali et al., 2021 | Single-arm trial | 34 | PASCAL | 30-d | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |

| | | | | | |
|-----------------------------------|------------------|-----|----------------------------|---------|---|
| Volz et al., 2022 | Observational | 11 | PASCAL | 3-month | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Lurz et al., 2021 | Single-arm trial | 85 | TriClip | 1-y | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Meijerink et al., 2021 | Observational | 21 | MitraClip, TriClip | 30-d | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Sugiura et al., 2021 | Observational | 44 | MitraClip, PASCAL | 30-d | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Stocker et al., 2021 | Observational | 236 | MitraClip, PASCAL | 1-y | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Cepas-Guillen et al., 2021 | Observational | 28 | MitraClip, TriClip | 3-mo | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Kitamura et al., 2021–2022 | Observational | 115 | MitraClip, TriClip, PASCAL | 1-y | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Nickenig et al., 2019 | Single-arm trial | 30 | Cardioband | 6-mo | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity \geq III, NYHA Class III/IV, TR Volume, |
| Davidson et al., | Single-arm trial | 30 | Cardioband | 30-d | TAPSE, Tricuspid Annulus |

| | | | | | |
|------------------------------|--|-----|--------------------|--------------|---|
| 2021 | | | | | Diameter, TR EROA, TR Severity ≥III, NYHA Class III/IV, TR Volume, |
| Körber et al., 2021 | Observational | 60 | Cardioband | 30-d | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity ≥III, NYHA Class III/IV, TR Volume, |
| Nickenig et al., 2021 | Single-arm trial | 61 | Cardioband | 30-d | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity ≥III, NYHA Class III/IV, TR Volume, |
| Mahowald et al., 2021 | Retrospective Cohort | 38 | MitraClip | 339 (125.25) | Mortality, heart failure hospitalization, reintervention |
| Low et al., 2021 | Retrospective Cohort | 120 | MitraClip, PASCAL | 30 | TR severity, (NYHA) functional class, major adverse cardiac, cerebrovascular events |
| Mehr et al., 2019 | Retrospective Cohort | 249 | MitraClip | 274 (187) | ehospitalization for heart failure with |
| Nickenig et al., 2017 | MultiCenter International single-arm trial | 64 | MitraClip, TriClip | 14 (18) | Postprocedural Events, major vascu |
| Nickenig et al., 2019 | Multicentre study prospective single-arm study | 85 | MitraClip, TriClip | 180 | 0 days post procedure, The primary |
| Ohno et al., y.d. | Retrospective Cohort | 146 | MitraClip | 660 (494) | ndpoint was freedom from death |
| Orban et al., 2018 | Dual centre single arm Cohort Study | 50 | MitraClip | 188.7 (22.1) | the mid-term device safety and dura |
| Sugiura et al., 2020 | Retrospective Cohort | 44 | MitraClip, PASCAL | 90 | Reduction in TR severity by at least one grade at 30 days. |
| Ali et al., 2020 | Prospective Cohort | 40 | MitraClip | 30 | major adverse cardiac and cerebrov |
| Aurich et al., 2021 | Prospective Cohort | 16 | PASCAL Ace | 30 | Postprocedural reduction in TR of at least 1 grade. |
| Baldus et al., 2022 | Multicenter prospective, single-arm Study | 74 | PASCAL | 30 | se events (MAEs) at 30 days, Reduc |
| Fam et al., 2019 | Nonrandomized, single-arm cohort study | 28 | PASCAL | 30 | ation of at least 1 device with post-p |

| | | | | | |
|----------------------------------|---|-------------------------------------|--------------------------|--------------|---|
| Freixa et al., 2022 | Multicenter Retrospective Cohort | 34 | TriClip | 90 | TR reduction of at least 1 grade assessed by transthoracic echocardiography at discharge. |
| Kalbacher et al., 2017 | Prospective Cohort | 766 | MitraClip | 395 (43.1) | In-hospital, one-year mortality, death, myocardial infarction ± stroke |
| Karam et al., 2019 | Retrospective Cohort | 126 | MitraClip | 187.75 (8.9) | Renal and liver function improvement. |
| Cai et al., 2020 | Single center, retrospective observational cohort | Total: 124 (T-TEER: 71; GDMT: 53) | TriClip (T-TEER) vs GDMT | 14–17 months | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity ≥III, NYHA Class III/IV, TR Volume, |
| TRILUMINATE, 2025 | RCT | Total: 572 (T-TEER: 285; GDMT: 287) | TriClip (T-TEER) vs GDMT | 24 months | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity ≥III, NYHA Class III/IV, TR Volume, |
| TRISCEND II Pivotal, 2025 | RCT | TTVT: 259; OMT: 133 | TTVR (EVOQUE) | 12 months | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity ≥III, NYHA Class III/IV, TR Volume, |
| Tri.Fr Trial, 2024 | RCT | 300 (TTVT: 152; OMT: 148) | T-TEER (TriClip) | 12 months | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity ≥III, NYHA Class III/IV, TR Volume, |
| TRICALVAL, 2020 | RCT | 28 (TTVT: 14; OMT: 14) | CAVI (Sapien XT) | 3 months | TAPSE, Tricuspid Annulus Diameter, TR EROA, TR Severity ≥III, NYHA Class III/IV, TR Volume, |

Table S2. Study Characteristics table

| Study | Representativeness | Non-Exposed Selection | Exposure Ascertainment | Outcome Absent at Start | Comparability | Outcome Assessment | Follow-up Duration | Adequacy of Follow-up | Total (9★) |
|------------------|--------------------|-----------------------|------------------------|-------------------------|---------------|--------------------|--------------------|-----------------------|------------|
| Ali et al., 2020 | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |

| | | | | | | | | | |
|-----------------------------|---|---|---|---|----|---|---|---|---|
| Aurich et al., 2021 | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Cai et al. (2020) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Cai et al. (2020) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Carcoana et al. (2024) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Cepas-Guillen et al. (2021) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Freixa et al. (2022) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Jan A. Krikken (2022) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Kalbacher et al., 2017 | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Karam et al., 2019 | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Kitamura et al. (2021–2022) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Kitamura et al. (2021) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Körber et al. (2021) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Low et al., 2021 | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Mahowald et al., 2021 | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Mehr et al., 2019 | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Meijerink et al. (2021) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Nickenig et al. (2017) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Ohno et al. | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Otto et al. (2021) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |

| | | | | | | | | | |
|-----------------------|---|---|----|---|----|---|---|---|---|
| Philipp Lurz (2018) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Ruf et al. (2021) | ☆ | ☆ | -+ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Stocker et al. (2021) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Sugiura et al. (2021) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Volz et al. (2022) | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Sorajja et al., 2023 | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |
| Stolz et al., 2022 | ☆ | ☆ | ☆ | ☆ | ☆☆ | ☆ | ☆ | ☆ | 9 |

Table S3. Quality assessment of included observational studies using the Newcastle–Ottawa Scale (NOS). Studies were evaluated across three domains: selection of study groups, comparability of cohorts, and ascertainment of outcomes/exposures. Higher scores indicate better methodological quality. ☆ indicate the presence of the required domain.

| Study (Author, Year) | Randomization Process | Deviations from Intended Interventions | Missing Outcome Data | Measurement of Outcome | Selection of Reported Result | Overall Risk of Bias |
|----------------------------|-----------------------|--|----------------------|------------------------|------------------------------|----------------------|
| TRIFR (2024) | Some concerns | Low risk | Low risk | Low risk | Some concerns | Some concerns |
| TRILUMINATE (2025) | Low risk | Some concerns | Low risk | Low risk | Low risk | Some concerns |
| TRISCEND II Pivotal (2025) | Some concerns | High risk | Low risk | Some concerns | Some concerns | High risk |
| TRICAVAL (2020) | Some concerns | High risk | Low risk | Some concerns | Some concerns | High risk |

Table S4. Risk of bias assessment of included randomized controlled trials using the Cochrane Risk of Bias (RoB 2) tool. Studies were evaluated across five domains: bias arising from the randomization process, deviations from intended interventions, missing outcome data, measurement of outcomes, and selection of the reported results.

| Study (Year) | Clearly Stated Aim | Consecutive Patients | Prospective Data Collection | Appropriate Endpoints | Unbiased Assessment | Adequate Follow-up | <5% Loss to Follow-up | Sample Size Calculation | Total (16) |
|--------------|--------------------|----------------------|-----------------------------|-----------------------|---------------------|--------------------|-----------------------|-------------------------|------------|
|--------------|--------------------|----------------------|-----------------------------|-----------------------|---------------------|--------------------|-----------------------|-------------------------|------------|

| | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|----|
| Carpenito (2022) | 2 | 2 | 2 | 2 | 1 | 2 | 1 | 2 | 14 |
| Philipp Lurz (2021) | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 15 |
| Donal E (2022) | 2 | 1 | 1 | 2 | 1 | 2 | 1 | 2 | 12 |
| Kodali et al. (2021) | 2 | 2 | 1 | 2 | 1 | 2 | 1 | 2 | 13 |
| Lurz et al. (2021) | 2 | 2 | 1 | 2 | 1 | 2 | 2 | 2 | 14 |
| Nickenig et al. (2019) | 2 | 2 | 2 | 2 | 1 | 2 | 1 | 2 | 14 |
| Davidson et al. (2021) | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 15 |
| Nickenig et al. (2021) | 2 | 1 | 1 | 2 | 1 | 2 | 1 | 2 | 12 |
| Nickenig et al., 2019 | 2 | 2 | 1 | 2 | 1 | 2 | 2 | 2 | 14 |
| Nickenig et al., 2017 | 2 | 2 | 2 | 2 | 1 | 2 | 1 | 2 | 14 |
| Orban et al., 2018 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 15 |
| Baldus et al., 2022 | 2 | 1 | 1 | 2 | 1 | 2 | 1 | 2 | 12 |
| Fam et al., 2019 | 2 | 2 | 1 | 2 | 1 | 2 | 1 | 2 | 13 |
| Kodali et al., 2021 | 2 | 2 | 1 | 2 | 1 | 2 | 2 | 2 | 14 |

Table S5. Methodological quality assessment of included non-randomized single arm studies using the Methodological Index for Non-Randomized Studies (MINORS) criteria.

| Outcome Measure | Figure | Subgroups | Total N | Pooled Estimate [95% CI] | Heterogeneity (I ²) | P-value (Subgroup) |
|------------------------------|--------|-----------|---------|--------------------------|---------------------------------|--------------------|
| TR Regurgitation Volume (mL) | S2 | Overall | 614 | -21.53 [-24.72, -18.35] | 80.50% | P=0.33 |
| | | MitraClip | 224 | -23.84 [-29.66, -18.03] | 63.80% | |

| | | | | | | |
|--------------------------|----|-----------|------|-------------------------|--------|--------|
| | | PASCAL | 120 | -17.10 [-23.47, -10.73] | 73.10% | |
| | | TriClip | 270 | -21.81 [-27.91, -15.71] | 85.50% | |
| TAPSE (mm) | S3 | Overall | 1179 | -0.74 [-1.27, -0.21] | 93.80% | P=0.50 |
| | | MitraClip | 400 | -0.92 [-1.43, -0.40] | 82.20% | |
| | | PASCAL | 150 | -0.45 [-1.15, 0.25] | 88.50% | |
| | | TriClip | 629 | -0.68 [-1.42, 0.05] | 95.90% | |
| 6-Minute Walk Test (m) | S4 | Overall | 1285 | 36.14 [23.85, 48.43] | 82.40% | P=0.04 |
| | | MitraClip | 362 | 48.98 [24.25, 73.72] | 84.40% | |
| | | PASCAL | 150 | 58.52 [29.32, 87.72] | 0.00% | |
| | | TriClip | 773 | 22.59 [11.07, 34.12] | 67.50% | |
| TR Severity (RR) | S5 | Overall | 1532 | 0.32 [0.26, 0.39] | 85.80% | P=0.90 |
| | | MitraClip | 465 | 0.34 [0.26, 0.44] | 67.20% | |
| | | PASCAL | 114 | 0.30 [0.21, 0.45] | 0.00% | |
| | | TriClip | 953 | 0.32 [0.22, 0.47] | 93.60% | |
| NYHA Class III/IV (Post) | S6 | Overall | 1668 | 0.26 [0.19, 0.34] | 77.30% | P=0.23 |
| | | MitraClip | 601 | 0.29 [0.21, 0.39] | 61.20% | |
| | | PASCAL | 114 | 0.30 [0.21, 0.42] | 0.00% | |
| | | TriClip | 953 | 0.20 [0.12, 0.36] | 87.10% | |
| Vena Contracta (mm) | S8 | Overall | 690 | -5.91 [-7.62, -4.19] | 97.90% | P=0.28 |
| | | MitraClip | 300 | -6.65 [-8.63, -4.68] | 95.80% | |
| | | PASCAL | 120 | -4.10 [-5.91, -2.29] | 87.70% | |
| | | TriClip | 270 | -5.87 [-9.26, -2.48] | 99.10% | |

| | | | | | | |
|-------------------------|-----|-----------|------|----------------------|--------|---------|
| EROA (cm ²) | S9 | Overall | 630 | -0.35 [-0.42, -0.27] | 93.80% | P=0.34 |
| | | MitraClip | 240 | -0.40 [-0.48, -0.32] | 80.40% | |
| | | PASCAL | 120 | -0.31 [-0.39, -0.23] | 76.90% | |
| | | TriClip | 270 | -0.31 [-0.46, -0.16] | 97.40% | |
| NYHA Class I/II (Post) | S10 | Overall | 1945 | 0.78 [0.72, 0.84] | 84.30% | P=0.009 |
| | | MitraClip | 722 | 0.73 [0.65, 0.80] | 73.10% | |
| | | PASCAL | 150 | 0.76 [0.60, 0.87] | 71.90% | |
| | | TriClip | 1073 | 0.86 [0.82, 0.89] | 62.00% | |

Table S6. Summary of the Outcomes