Percutaneous or (versus) surgical pulmonary valve implantation. A systematic review and meta-analysis of currently available clinical evidence.

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Background

- Percutaneous PVI has became available in the last twelve years.

- In literature there are no studies on meta-analysis of surgical and percutaneous therapy.

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Background

- Large data set comparing these two techniques are lacking

- Few systematic reviews and meta-analysis studies are reported in the field of pediatric cardiology/cardiac surgery
Clinical Question & Objectives

- Clinical Question
  Is there any difference in procedural results between surgical and percutaneous treatment?

- Objectives
  to perform a meta-analysis of all relevant studies reporting data on surgical and percutaneous PVI
Methods

- Databases: Pubmed, Google Scholar, Biomed Central

- Search updated December 2012

- Search terms:
  - ‘pulmonary valve’, “surgery”, “transcatheter”, “percutaneous”

- Inclusion criteria for studies:
  - patients aged >5 years,
  - Papers published between 2005 and 2012
  - Reporting on > 20 pts
Methods

- Data collection
  - Pre-specified forms used to collect data on baseline characteristics and outcomes
  - Data abstracted by two independent and unblinded reviewers (GB, FP)
  - Data abstracted: authors, journal, years of conduct and publication, study design, sample size, patient characteristics, raw numbers for death, total complication and major adverse cardiovascular events, length of hospital stay
Methods

- Statistical methods
  - performed using Review Manager 4.2.4
  - Pooled estimated for odds ratios computed according to random effect methods
  - Continuous variables compared using random effect inverse variance weighting method
  - Statistical inconsistency appraised with I2
  - Reported values were two-tailed and results were considered statistically significant at the 0.05 level.
  - Quality of included studies was appraised according to the Cochrane Collaboration methods
Methods

- Primary outcome (early and at follow-up):
  - Death
  - Major complications

- Secondary outcomes:
  - redo-procedures
  - incidence of endocarditis

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Results

320 citations from initial search

13 articles retrieved

307 excluded as non-relevant at citation level

23 studies selected

1 study excluded

Total of 2494 patients

1777 pts with surgical PVI

717 pts with percutaneous PVI

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Results: Primary outcomes

Death

A total of 20 early deaths were encountered:
3 in the PERC group and 17 in the SURG group

PERC 0.4% (95% CI 0.2-0.6)  
p<0.01

SURG 1% (95% CI 0.8-1.2)
Results: Primary outcomes

Major total complication rate

5.1% (95% CI: 3.5-6.7)  (p<0.01)

9% (95% CI: 8.3-9.7%)

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Results: Follow-up

Late death

kt 1.2 % (95% CI 0.8-1.6 %)

surgery 0.8 % (95% CI 0.54-1.6%)

Redo procedures

kt 5.4 % (95% CI 4.6-6.2 %)

surgery 5.1 % (95% CI 4.6-5.6%)

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Results: Follow-up

Endocarditis

kt  11 pts  1.5 % (95% CI 1.1-1.95 %)

p <0.001

surgery  2 pts  0.11 % (95% CI 0.03-0.19%)

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Sensitivity analyses

- Testing for publication bias yielded non-significant results (P=0.107 at Egger test)
- Excluding one study at a time, did not determine major changes in direction or magnitude of statistical findings
Limitations

Inherent limitations of individual studies within meta-analysis impact on overall result

- Retrospective, unblinded, non-randomized, non paired
- Single center studies
- Quite wide range of publication dates (2005--2012)
- Different groups of patients with different anatomies (surgery--mostly native RVOT/kt---mostly conduits)
Conclusions

The largest cohort to date of patients undergoing treatment of RVOT dysfunction shows that treatment by a percutaneous approach “apparently” has a significantly lower rate of both early death and major early post-procedural complications.

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Conclusions

The largest cohort to date of patients undergoing treatment of RVOT dysfunction shows that long term results looks similar

incidence of endocarditis is significant in transcatheter patients

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Thank you for your attention