

Surgical or endovascular intervention for aortic coarctation in adult native, residual or re-coarctation?

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Surgical or endovascular intervention for aortic coarctation in adult native, residual or re-coarctation?

[Är öppen kirurgi eller kateterbehandling att föredra vid nativ, rest- eller re-coarctation av aorta hos vuxna?]

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Abbreviations

CoA coarctation of the aorta

ACHD adult congenital heart disease

1. Summary of the Health Technology Assessment

Background

Coarctation of the aorta (CoA) is a congenital vascular malformation occurring in approximately 0.05% of all live births. CoA is most often detected early in life and corrected by surgery or endovascular treatment. It may also be diagnosed later in life. After correction, there is a risk of postoperative complications in the descending aorta and the aortic arch and/or of hypertension later in life. Over the last 20 years many centers have shifted from surgical to endovascular treatment of CoA in the adult. A perceived high risk associated with open surgery in particular repeat surgery for CoA, and a convenience argument for the patient have facilitated this shift.

Objective

To describe and assess the evidence for endovascular stent treatment as compared to open surgery for native aortic coarctation, residual or re-coarctation in adults concerning mortality and serious complications.

Search methods and study selection criteria

Systematic searches were performed in PubMed, Embase, the Cochrane Library, and a number of HTA-databases. Reference lists of relevant articles were scrutinised for additional references. Studies were required to be a systematic review (SR), a controlled study or a case series with ≥ 40 patients with $\geq 50\%$ adults published after 1990. Case series were used only for analysis of complications/adverse events. The quality of evidence was graded using the GRADE system.

Main results

Twelve articles met the inclusion criteria (PICO), one SR including case series only, three cohort studies with controls and seven case series. There were no randomized controlled trials. Long-term mortality was 0–3% after endovascular (follow-up 1–6 years) and 0–1% after surgical (follow-up 2–18 years) reconstruction in the cohort studies. There was no perioperative mortality in the cohort studies. Technical success rate averaged 98.7% after endovascular and was 100% in surgical series in the SR and was 100% in both groups in the cohort studies. The average blood pressure at follow-up was similar in the endovascular and surgical series in one cohort study.

In the SR, the reintervention rates were 10% and 1% after endovascular and surgical reconstruction respectively. In the larger cohort study there were 14% reinterventions after endovascular and 12.5% after surgical reconstruction. In the case series, the reintervention rate was 15.8% (range 5.7–44%) endovascular reconstructions. In the SR, aortic wall complications, mainly aneurysms, occurred in 14/464 (3%) of endovascular reconstructions as compared to no aortic wall complications (mean follow-up three times longer) after surgical reconstructions. The frequency of aortic wall complications ranged between 1.6–7% after endovascular reconstruction in the case series.

Hospital stay ranged between 2.1–7.8 days after endovascular and 9.6–11.8 days after surgical reconstruction.

The quality of evidence was low for all studied outcomes (GRADE $\oplus\text{○○○}$)

Concluding remarks

This report assessing endovascular and surgical treatment for native aortic coarctation or re-coarctation in adults shows that it is uncertain whether there is little or no difference regarding perioperative and long-term mortality, technical success rate and blood pressure at follow-up. It is uncertain whether there are more reinterventions and aortic wall complications and whether hospital stay is shorter after endovascular reconstruction. The quality of evidence was low for all studied outcomes (GRADE $\oplus\text{○○○}$) Further studies with long-term follow-up after endovascular reconstruction are needed.

2. Svensk sammanfattning

Bakgrund

Coarctatio aortae (CoA) är en medfödd missbildning som förekommer hos 0,05% av alla levande födda barn. Tillståndet upptäcks oftast mycket tidigt i livet och korrigeras, om behövt, med kirurgi eller endovaskulär behandling i barndomen, men ibland ställs diagnosen först senare i livet. Efter åtgärd finns en risk för postoperativa komplikationer i aortabågen eller thorakala aorta och/eller hypertoni senare i livet. De senaste 20 åren har på många stora centra behandlingsmetoden ändrats från kirurgisk till endovaskulär behandling av CoA hos vuxna. En förmodat högre risk med öppen kirurgi, inte minst vid reoperation, och bekvämlighetsargument för patienten har påskyndat denna förändring.

Syfte

Att utvärdera den vetenskapliga dokumentationen för endovaskulär stentbehandling jämfört kirurgisk behandling för nativ, re- eller restkoarktation hos vuxna avseende mortalitet och allvarliga komplikationer.

Sökning och studieselection

Systematisk sökning gjordes i PubMed, Embase, Cochrane Library och ett antal HTA-databaser. Referenslistor i relevanta artiklar granskades avseende ytterligare referenser. Studier inkluderades om de var en systematisk översikt (SR), en kontrollerad studie eller en fallserie med ≥ 40 patienter och $\geq 50\%$ vuxna publicerad efter 1990. Fallserier användes endast för analys av komplikationer. Det vetenskapliga stödet bedömdes enligt GRADE.

Resultat

Tolv artiklar uppfyllde kriterierna (PICO), en SR som innehöll endast fallserier, tre kohortstudier med kontroller och åtta fallserier. Det fanns inga randomiserade kontrollerade studier.

Långtidsmortalitet var 0 – 3% efter endovaskulär (uppföljning 1 – 6 år) och 0 – 1% efter kirurgisk (uppföljning 2 – 18 år) rekonstruktion i kohortstudierna. Ingen perioperativ mortalitet rapporterades i kohortstudierna. Technical success var genomsnittligt 98,7% vid endovaskulär och var 100% vid kirurgisk rekonstruktion i den systematiska översikten och var 100% i båda grupperna i kohortstudierna. Genomsnittligt blodtryck vid långtidsuppföljning var i samma storleksordning i de båda grupperna.

I den systematiska översikten rapporterades 10% respektive 1% reinterventioner efter endovaskulär och kirurgisk åtgärd. I en större kohortstudie var motsvarande siffror 14% och 12,5%. I fallserierna rapporterades reinterventioner efter 15,8% (range 5,7% - 44%) endovaskulära åtgärder.

Aortaväggskomplikationer, främst aneurysm, uppträdde efter 14 (3%) av 464 endovaskulära åtgärder för CoA jämfört med inga sådana komplikationer efter kirurgisk åtgärd trots tre gånger längre uppföljningstid. Frekvensen av aortaväggskomplikationer varierade mellan 1,6 – 7% efter endovaskulär intervention i fallserierna. Vårdtiden varierade mellan 2,1 – 7,8 dagar versus 9,6 – 11,8 dagar vid endovaskulär respektive kirurgisk intervention.

Det vetenskapliga underlaget är otillräckligt för samtliga studerade utfall (GRADE ⊕○○○)

Slutsatser

Rapporten avseende endovaskulär respektive kirurgisk åtgärd för nativ, re- eller restkoarktation visar att det är osäkert huruvida det är lite eller ingen skillnad avseende peroperativ och långtidsdödlighet, technical success och långtidseffekt på blodtrycket. Det är vidare osäkert huruvida det är fler reinterventioner och mer aortaväggskomplikationer samt kortare vårdtid för endovaskulärt behandlade patienter. Det vetenskapliga underlaget är otillräckligt för samtliga studerade utfall (GRADE ⊕○○○) Det behövs ytterligare, stora studier med långtidsuppföljning efter endovaskulär behandling av CoA.

Summary of the Health Technology Assessment (1&2) from The Regional Health Technology Assessment Centre (HTA-centrum)

The Regional Health Technology Assessment Centre (HTA-centrum) of Region Västra Götaland, Sweden (VGR) has the task to make statements on HTA reports carried out in VGR. The statement should summarise the question at issue, results and quality of evidence regarding efficacy and risks, and economical and ethical aspects of the particular health technology that has been assessed in the report.

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Head of HTA-centrum of Region Västra Götaland, Sweden, 2014-05-21

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3. Participants in the project.

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Who posed the question?

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Are there any conflicts of interest for the proposer or any of the participants in the work group?

None declared

Projecttime

HTA was accomplished during the period of 2013-09-11 – 2014-05-21

Last search updated in October 2013

4. Which health technology or method will be assessed?

Disease/disorder of interest and its degree of severity

Coarctation of the aorta (CoA) is a congenital malformation that may occur as a sole entity or may occur in combination with other cardiac and/or vascular malformations. Treatment options may be governed and determined by other conditions. The present report covers only CoA when it is occurring as the only or the clinically dominating cardiovascular problem. CoA is most often detected early in life and corrected by surgery or endovascular treatment. It may also be diagnosed later in life, frequently in association with hypertension and/or dissection (Oliver J et al, JACC 2004;44:1641-7). Despite excellent surgical results, there is a risk of postoperative complications of the descending aorta and the aortic arch. There is also a remaining high risk of developing hypertension later in life. About half of all patients with CoA have developed hypertension 30-40 years postoperatively (Canniffe C et al, Int J Cardiol 2013;167:2456-61). Patients with CoA frequently have bicuspid aortic valves and therefore the presence or absence of aortic valve morbidity must be assessed (Clair M et al, Cong Heart Dis 2013, 14 June 2013, e-pub). Over the last 20 years, endovascular treatment has become the treatment of choice for residual, re- or native coarctation in the adult in most institutions, despite a lack of randomized, controlled studies.

- Risk of premature death
- Risk of permanent illness or damage, or reduced quality of life
- Risk of disability and health-related quality of life

Prevalence and incidence of the disease/disorder

Coarctation of the aorta as a major feature of a congenital cardiovascular malformation is observed in 5-8 % of patients with congenital heart disease i.e. in 0.045-0.07 % of all live births. In Region Västra Götaland (1.1 million adults) it is estimated that 0.03% of adults, i.e. 330 patients have CoA. The number of residual or re-coarctations has not been adequately described. The prevalence of hypertension among adult patients today is less well known but reported to 35%, according to the Swedish registry SWEDCON. This prevalence (<http://www.ucr.uu.se/swedcon/index.php/arsrapporter/2011>) is lower than what has been reported in earlier studies. The frequencies of residual coarctation and re-coarctation are varying and not well described in contemporary cohorts of patients operated on with the type of corrective surgery commonly used in Sweden. The prevalence of hypertension in this patient population is not known.

Present treatment of the disease/disorder.

Many centers have shifted from surgery to endovascular treatment of residual- re- or native coarctation in the adult during the last 20 years. This therapeutic shift has been based on an extrapolation of clinical results of endovascular techniques on pediatric patients and on a convenience argument for the patient. In addition, a perceived high surgical risk associated with coarctation surgery, in particular repeat surgery, has facilitated this shift from surgical to endovascular treatment.

Number of patients per year who undergo current treatment regimen?

Endovascular treatment of residual, re- or native coarctation of the aorta is performed in less than 10 cases per year in the tertiary Adult Congenital Heart Unit in Göteborg, covering approximately half the Swedish population. During the last 10 years only two adult patients who had undergone open surgery, could be identified in the surgical registry at the department of thoracic surgery.

The normal pathway of a patient through the health care system

Patients are either identified in the outpatient clinic, caring for most patients with CoA in Region Västra Götaland or are referred to the Adult Congenital Heart Unit for assessment. Patients are referred mainly from Region Västra Götaland but also from other parts of Sweden. The indication is either the presence of a residual, re- or native- coarctation defined by > 20 mmHg pressure difference between arms and legs, morphological changes observed on MR or CT-scanning and/or uncontrolled or poorly regulated hypertension in spite of medication. After workup, the patient is presented at a multidisciplinary conference with thoracic/congenital surgeons, interventional cardiologists and a cardiologist with training in adult congenital heart disease, to decide the preferred treatment according to international and local (consensus based) guidelines.

Actual wait time in days for medical assessment /treatment

The waiting time is frequently 4-8 weeks but never exceeding 12 weeks, from decision to intervention (endovascular or surgical)

5. Present Health Technology

Name/description of the health technology at issue

Endovascular treatment of residual, re- or native CoA is performed by introducing a catheter into the femoral artery and advancing it to the descending aorta. A balloon tipped catheter, in general with a stent mounted, is advanced into the descending aorta and, when properly positioned the balloon is inflated and the stent deployed, dilating the coarctation. The stent is used to prevent dissection and elastic recoil. The procedure is done under general anesthesia.

The work group's understanding of the potential value of the health technology

Today, endovascular treatment of CoA in the adult is a well established procedure associated with a limited risk of complications and in general good clinical results, as described in several large case series. The endovascular technique has advantages of shorter hospitalization, probably lower direct costs and equal early clinical results as compared to surgery. In many instances a life-time perspective will emphasize the importance of limiting the number of thoracotomies/sternotomies performed. Technical difficulties reduce the willingness to treat a residual or re-coarctation concomitantly with other cardiac surgery. This is due to the difficulty in gaining access to the descending aorta through a sternotomy. Thus, sequential procedures may be needed and using both surgery and endovascular techniques may be optimal for anatomical reasons. Some coarctations are not suitable for endovascular treatment and surgery will be the first choice. Comparative studies are very few in isolated, pure, residual re- or native coarctation in the adult. It is not believed that proper randomized studies will ever be done (no ongoing trials) and the techniques may today be considered complementary.

The long-term results after surgery in children or young adults, are good and fairly well described. The long term results after endovascular treatment in children have been described while less is known about long-term morbidity and mortality when performed in the adult. The frequency of hypertension after endovascular treatment for CoA has not been assessed.

The central question for the current HTA project in one sentence

Is endovascular stent treatment better than open surgery for native aortic coarctation or re-coarctation in adults concerning mortality and serious complications?

PICO P= Patients, I= Intervention, C= Comparison, O=Outcome

PICO

P = Adults with native, re- or residual coarctation

I = Endovascular stent

C = Open surgery

O = Critical:

Mortality, technical success,

Important:

Hypertension, Health related quality of life, re-intervention, aortic wall complication (re-coarctation, aneurysm formation, intimal tears, dissection),

Less important:

Other complications (cardiovascular: stroke, peripheral emboli and access artery injury; technical complications: stent migration, balloon rupture, suture dehiscence, paraplegia),
Hospital stay

Study design Studies with $\geq 50\%$ adults or with results split by age groups.

RCT

Systematic Reviews

Non-randomized controlled studies

Case series ≥ 40 patients

Publication years

1990 – 2013

Languages

English, Scandinavian languages

Name/description of the health technology at issue

Endovascular treatment of coarctation

6. Review of Quality of Evidence

Search strategy, study selection and references (Appendix 1)

During September 2013 two librarians (TS and JP) performed systematic searches in PubMed, Embase, the Cochrane Library, and a number of HTA-databases. Reference lists of relevant articles were also scrutinised for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are accounted for in appendix 1. The librarians conducted the literature searches, selected studies and independently assessed the obtained abstracts and a first selection of full-text articles for inclusion or exclusion. Any disagreements were resolved in consensus. The remaining articles were sent to the project participants, who read the articles independently and then decided in a consensus meeting which articles that should be included.

The literature search identified a total of 751 articles (after removal of duplicates). The librarians then excluded 680 articles after reading their abstracts. Another 52 articles were excluded by the librarians after reading the articles in full text. The remaining 19 articles were sent to the work group, and 11 of them were finally included in the report. Three of the articles are cohort studies and have been critically appraised using checklists from SBU (Swedish Council on Health Technology Assessment). One of the articles is a systematic review and is critically appraised using the AMSTAR checklist for systematic reviews.

Included studies – design and patient characteristics (Appendix 2)

Eleven studies were included, one systematic review, three cohort-studies, seven case series.

Excluded articles – (Appendix 3)

Outcome tables – (Appendix 4)

Summary of Findings, SoF-table (Appendix 5)

Ongoing research

We identified 16 trials of CoA in clinicaltrials.com on December 12 2013, using search terms (*coarctation OR coarctations OR re-coarctation OR re-coarctations OR recoarctation OR recoarctations*). Seven were described as active, not recruiting. There were three studies of stents without results. No randomized study of endovascular treatment vs surgery reported in Chlinical.trials.com

Which medical societies or health authorities recommend the new health technology?

- The National Board of Health and Welfare
- Medical societies
- Other health authority

Which medical society or health authority?

European Society of Cardiology

Describe briefly the present knowledge of the health technology

We included 11 articles, one systematic review, three cohort studies and seven case series.

Critical outcomes

Mortality.

Long-term mortality was reported in one SR, two cohort studies and two case series. Long-term mortality was 0 – 1% after surgical (follow-up from two to 18 years) and 0 – 3% after endovascular (follow-up from one to 6.5 years) reconstruction in the cohort studies.

Perioperative mortality was reported in two cohort studies and six case series. There was no perioperative mortality in either group in the cohort studies and perioperative mortality ranged from zero to 1.5% in the endovascular case series.

Conclusion: It is uncertain whether there is little or no difference in perioperative and long-term mortality after endovascular as compared to surgical reconstruction for CoA.

Very low quality of evidence (GRADE ⊕○○○)

Technical success,

The technical success was reported in one SR, one cohort and seven case series. Mean technical success rate was 98.7% after endovascular and was 100% in surgical series in the SR and was 100% in both groups in the cohort studies.

Conclusion: It is uncertain whether there is little or no difference in technical success rate after endovascular as compared to surgical reconstruction for CoA.

Very low quality of evidence (GRADE ⊕○○○)

Important

Hypertension

Five studies reported on hypertension, one cohort and four case series. The average blood pressure at follow-up was similar in the endovascular and surgical series (129±23 and 133±21 respectively) in the cohort study. Conclusion: It is uncertain whether there is little or no difference in the frequency of hypertension during long-term follow-up after endovascular as compared to surgical reconstruction for CoA. Very low quality of evidence (GRADE ⊕○○○)

Health Related Quality of Life

No studies reported health related quality of life

Re-intervention

Reinterventions rate was reported in one SR, two cohort studies and seven case series. In the SR, reinterventions were needed in 10% after endovascular and 1% after surgical reconstruction. In one cohort study (n= 59/40) there were 14% reinterventions after endovascular interventions and 12% after surgical reconstruction. There were no reinterventions in one small (n=5/6) cohort study. In the case series, the mean reintervention rate was 15.8% (range 5.7 – 44%) after endovascular reconstructions.

Conclusion: It is uncertain whether there are more reinterventions after endovascular as compared to surgical reconstruction for CoA.

Very low quality of evidence (GRADE ⊕○○○)

Aortic wall complications

Complications in the aortic wall were reported in one SR, one cohort and six case series. In the SR, such complications, mainly aneurysms, occurred in 14 (3%) of 464 endovascular reconstructions (2.9 years mean follow-up) as compared to no aortic wall complications (mean follow-up 7.8 years) after surgical reconstructions. There was one aortic wall complication in both groups in one small cohort study (n= 5/6). The frequency of aortic wall complications ranged between 1.6 – 7% after endovascular reconstruction in the case series, including two fatal aortic ruptures.

Conclusion: It is uncertain whether aortic wall complications are more common after endovascular as compared to surgical reconstruction for CoA.

Very low quality of evidence (GRADE ⊕○○○)

Other complications

The most commonly reported complication was stent migration which occurred in 55 of 1294 (4.1%) cases, and rupture of the balloon, 16 of 1294 (1.2%) cases.

Conclusion: It is uncertain whether other complications are more common after endovascular as compared to surgical reconstruction for CoA.

Very low quality of evidence (GRADE ⊕○○○)

Less important

Hospital stay

The length of hospital stay was reported in two cohort studies. Hospital stay ranged between 2.1 - 7.8 days after endovascular and 9.6 - 11.8 days after surgical reconstruction.

Conclusion: It is uncertain whether hospital stay is shorter after endovascular as compared to surgical reconstruction for CoA.

Very low quality of evidence (GRADE ⊕○○○)

7. Ethical consequences

Ethical consequences

Endovascular reconstruction for CoA has already been introduced as the preferred method despite very low quality of evidence for patient benefit and complications. The long-term effectiveness and risks with endovascular reconstruction are poorly known, raising ethical questions. Using a technique with less wellknown long-term effects may be problematic.

8. Organisation

When can this new health technology be put into practice?

This technology is already being used

Is this technology used in other hospitals in Region Västra Götaland of Sweden?

No.

According to the work group, will there be any consequences of the new health technology for personnel?

The prevalence of adult coarctation is low and management will probably have a small impact on overall resource-use.

Will there be any consequences for other clinics or supporting functions at the hospital or in the whole Region Västra Götaland of Sweden?

No consequences. Concentration to one or two national units would yield centers with more experience and higher volume.

9. Economy aspects

Present costs of open surgery

The cost per patient is between 225.000 and 334.000 (average 280.000 SEK) for surgical patients for the initial repair.

Costs of endovascular treatment

The costs per patient for endovascular treatment is 100.000 SEK. The longterm cost is less well known; reinterventions may increase the long term cost in the endovascular group.

Total change of cost

Assuming a four times higher reintervention rate for endovascular treatment compared to 6.5% (Brown 2013) after surgical treatment and that reinterventions have equal cost to primary interventions the total cost for 15 patients would be $100.000 \times 15 + 4 \times 100.000 = 1.900.000$ SEK for endovascular treatment vs $15 \times 280.000 + 280.000 = 4.480.000$ SEK. Thus, with this example of an assumed fourfold increased risk of reintervention with endovascular treatment the total cost of endovascular treatment can be estimated at about 50% of that of surgery in comparable patients. This estimate does not include costs for the treatment of late complications.

Can the new technology be adopted and used within the present budget (clinic budget/hospital budget)?

Endovascular interventions are already being performed as routine

Are there any available analyses of health economy? Cost advantages or disadvantages?

No health economic data exists

10. Unanswered Questions

Important gaps in scientific knowledge?

The long-term effect on blood-pressure is less well known for both techniques, in particular for endovascular treatment.

The risk of recurrent coarctation after stenting for native adult coarctation is not well described and is of paramount importance for the selection of the proper mode of treatment

The effects on health related quality of life of endovascular treatment are not known, neither per se, nor in comparison to post-surgical intervention

The presence of conventional risk-factors i.e. impaired glucose tolerance, hyperlipdemia, subclinical hypertension and physical inactivity may affect the long-term risk for major atherosclerotic aortic disease. This has not been studied.

Is there any interest in your own clinic/research group/organisation to start studies/trials within the research field at issue?

We are currently conducting studies to assess the clinical short-term complications after stenting of coarctations as well as refining radiological methods to identify patients for stenting. We would be very interested in pursuing a project of long-term follow-up of patients who have previously undergone stenting, and compare to previous surgical patients. Such a project is currently not planned but being discussed. We would also be very interested in assessing the presence of conventional arteriosclerosis risk-factors and subclinical hypertension. Such a project is ongoing regarding mainly other patients with congenital heart disease. Whether the presence of such risk factors or the existence of a coarctation per se is associated with subsequent development of coronary artery disease is sparsely studied. This research question may be adressed within existing registry networks (GOCARTS node) in Göteborg.

The overall change in practice by the introduction of endovascular treatment has not been described. While it is believed that endovascular treatment may delay or postpone other surgical interventions i.e. aortic valve replacement, no one has actually shown this to be the case. The existing registries in Sweden would make it possible to study these questions.

Appendix 1, Search strategy, study selection and references

Question at issue:

Is endovascular stent treatment better than open surgery for native aortic coarctation or re-coarctation in adults concerning mortality and serious complications?

PICO

P = Adults with native, re- or residual coarctation

I = Endovascular stent

C = Open surgery

O = Mortality*, Technical success*, Hypertension, Health related quality of life, Re-intervention, Aortic wall complication (re-coarctation, aneurysm formation, intimal tears, dissection), Other complications (cardiovascular: stroke, peripheral emboli and access artery injury; technical complications: stent migration, balloon rupture, suture dehiscence, paraplegia), Hospital stay

* *Critical outcome*

Eligibility criteria

Study design:

RCT

Systematic Reviews

Non-randomized controlled studies

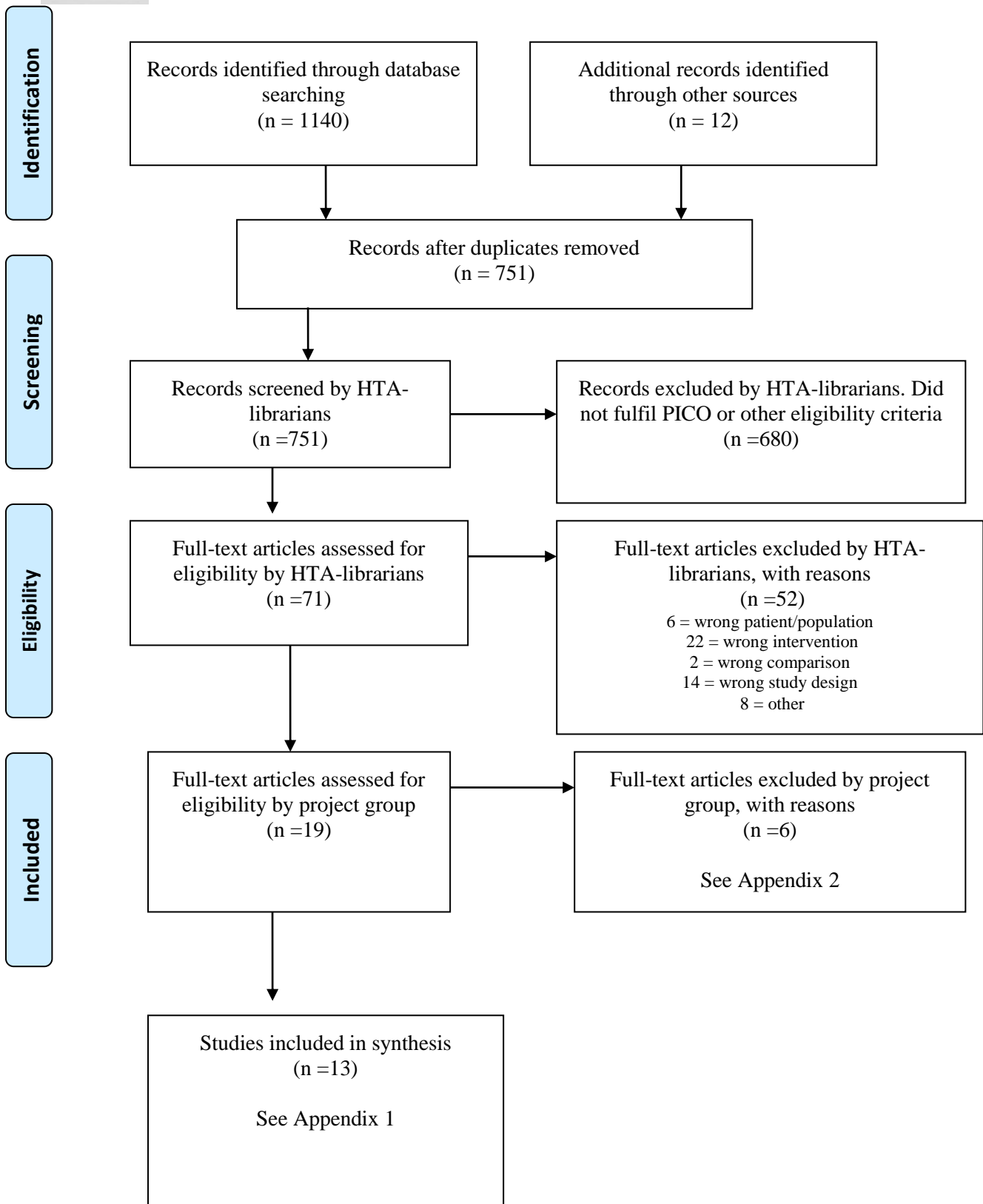
Case series ≥ 40 pat, with $\geq 50\%$ adults

Language:

English, Swedish, Norwegian, Danish

Publication date: 1990 -

Selection process – flow diagram



Search strategies

Database: PubMed

Date: 2013-09-18

No of results: 513

Search updated:

Search	Query	Result
#13	Search #9 NOT #8 Filters: Publication date from 1990/01/01; Danish; English; Norwegian; Swedish	513
#10	Search #9 NOT #8	686
#9	Search #6 NOT #7	690
#8	Search ((animals[mh]) NOT (animals[mh] AND humans[mh]))	3818225
#7	Search Editorial[ptyp] OR Letter[ptyp] OR Comment[ptyp]	1262720
#6	Search #3 AND #4 AND #5	713
#5	Search stent or stents or stenting or endovascular or endovascular procedures[MESH] or angioplasty or angioplasties or catheter-based or transcuteaneous	159661
#4	Search adult or adults or grown-up or grown-ups or elderly or old or older	6202845
#3	Search coarctation or coarctations or re-coarctation or re-coarctations or recoarctation or recoarctations	10199

Database: EMBASE (OVID SP)

Date: 2013-09-18

No of results: 573

Search updated:

#	Searches	Results
1	exp aorta coarctation/	10300
2	(coarctation or coarctations or re-coarctation or re-coarctations or recoarctation or recoarctations).ti,ab.	9002
3	1 or 2	12439
4	exp adult/	4546039
5	(adult or adults or grown-up or grown-ups or elderly or old or older).ti,ab.	2054508
6	4 or 5	5806858
7	exp stent/	93728
8	exp endovascular surgery/	16904
9	exp angioplasty/	66358
10	(stent or stents or stenting or endovascular or angioplasty or angioplasties or catheter-based or transcuteaneous).ti,ab.	156052
11	7 or 8 or 9 or 10	194281
12	3 and 6 and 11	1000
13	limit 12 to (embase and (danish or english or norwegian or swedish) and yr="1990 -Current" and (article or conference paper or note or "review"))	573

Database: The Cochrane Library

Date: 2013-09-18

No of results: 44

ID	Search	Hits
#1	coarctation or coarctations or re-coarctation or re-coarctations or recoarctation or recoarctations:ti,ab,kw (Word variations have been searched)	44
#2	MeSH descriptor: [Aortic Coarctation] explode all trees	36
#3	#1 or #2	44

Database: CRD

Date: 2013-09-18

No of results: 10

ID	Search	Hits
#1	(coarctation OR coarctations OR re-coarctation OR re-coarctations OR recoarctation OR recoarctations)	10

The web-sites of **SBU, Kunnskapssenteret** and **Sundhedsstyrelsen** were visited

2013-09-18

Nothing relevant to the question at issue was found

Reference lists

A comprehensive review of reference lists brought 12 new records

Reference lists

Included studies:

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Excluded studies:

Chessa M, Carrozza M, Butera G, Negura D, Piazza L, Giamberti A, et al. The impact of interventional cardiology for the management of adults with congenital heart defects. *Catheter Cardiovasc Interv.* 2006;67(2):258-64.

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Appendix 2 – Included studies – design and patient characteristics.

Author, Year, Country	Study Design	Study Duration (years)	Study Groups; Intervention vs control	Patients (n)	Mean Age (years)	Men (%)	Outcome variables
Carr JA, 2006,	Systematic review of case series	10	Endovascular or surgery	Endo: 633 pts, 16 studies Surg: 213 pts, 6 studies	Endo: 22y Surg: 37	unknown	Mortality, reinterventions
Roselli, 2012, USA	Cohort	12	Surgery hybrid endovascular	110 Surgery (n=40) hybrid (n=11) endovascular (n=59)	38	65	Technical success, complications
San Norberto Garcia, 2010, Spain	Cohort	10	Surgery, endovascular	11	46	82	Success rate, complications
Tan, 2005, UK, Singapore	Cohort	1	Endovascular, previous surgery	24 (13 resp 11)	30/39	unknown	Hypertension
Bentham JR, 2013, UK	Case series	10 years	endovascular	40	24,9	72	Medium term blood pressure
Chakrabati, 2010, UK	Case series	6	endovascular	88	20,6	48	CT of aorta
Chessa M 2005, Italy	Case series	7	endovascular	71	21,8	62	Gradient at FU (3 years), complications
Forbes TJ, 2007, USA, Brazil	Case series	16	endovascular	555	15	unknown	Procedural success, complications
Holzer R, 2010, USA, Brazil	Case series	9	endovascular	302	15	70	Procedural success, recurrences
Kraseman, 2011	Case series	13	endovascular	68	25,2	62	Technical success, complications
Szutnik, 2010, Poland	Case series	15	endovascular	203	15	unknown	Pressure gradient, reintervention

Project: Coarctation
Appendix 3 Excluded studies

Study (author, publication year)	Reason for exclusion
Chezza M, 2006	Report on single center endovascular series. Data on CoA already reported in previous article 2005.
Eicken A, 2006	17/43 (40%) of patients above 18 years of age. PICO demands at least 50%.
Forbes TJ, 2007	Outcome reported only as imaging result. No information on age of participants.
Golden AB, 2007	Review on previously published data.
Qureshi AM, 2007	52/153 (35%) of patients above 18 years of age. PICO demands at least 50%.
Shah L, 2005	Small material 44patients with mean age 16,9 years and 32% being below 10 years of age from a Children´s Hospital. PICO demands > 50% being above 18 years, which is not probable (though exact number of patients above 18 is not reported) .
Pádua Laryssa, 2012	Cochrane analysis, aimed to included only RCTs, found none
National Institute for Clinical E. Balloon angioplasty with or without stenting for coarctation or recoarctation of the aorta in adults and children. London: National Institute for Clinical Excellence (NICE); 2004	Evaluated one small RCT in pediatric patients, two case series with less than 100 patients and 2 large case series with dominating pediatric patients. PICO required at least 50% adult patients and excluded case series with less than 100 patients
NICE interventional procedure guidance 74, 2004	Technical guidelines, summary of above

Project:Coarctation

Appendix 4:1

Outcome variable: Long term mortality in coarctation repair

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n= Surg/endo	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Endovascular stent	Surgery				
Carr, 2006	USA	Systematic review of case series	464/213		0-3%	0-1%	SR based on case series and observational studies. Endovascular stent and angioplasty+stent in 13 studies of 464 patients, f u from 12 to 79 months. Surgical treatment in 6 studies of 213 patients with fu 2 to 18 years. Results are presented as mortality range in included studies.Major problems of directness, study limitations and precision for included studies.	-	-	-
Garcia, 2010	Spain	Cohort study	5/6	0	0% (53 months)	0% (70 months)	Non randomized contemporary controls. Choice of approach is dictated by indication. Mean time to f u was 53 months in endovascular group and 70 months in surgical group	?	-	-
Roselli, 2012	USA	Cohort study	70/40	0	See comments	See comments	Three separate case series: surgical (40 patients), hybrid and endovascular (11+59 patients). Choice of approach is dictated by indication. Result for hybrid approach is included in endovascular stent. Total of three deaths (3%) at late f u (median of 56 months). One death in patient operated with hybrid approach 4 months postoperatively due to hypertensive crisis. One death of unknown cause in an endovascular stent treated patient. One death due to heart failure, unknown treatment group.	?	-	-
Bentham, 2013	UK	Case series	40		2,5% (1 year)		One death at 1 yr f u due to non cardiac causes.			
Chessa, 2005	Italy	Case series	71		0,15% (3,1 years)		One perioperative death. F u at median of 3,1 years (6 months-7 years)			

Project:Coarctation

Appendix 4:2

Outcome variable: Perioperative mortality in coarctation repair

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Endovascular stent	Surgery				
Garcia, 2010	Spain	Cohort study	5/6	0	0%	0%	Five endovascular, 6 surgical. Non randomized contemporary controls. Choice of approach is dictated by indication.	?	-	-
Roselli, 2012	USA	Cohort study	70/40	0	0%	0%	Three separate case series: surgical (40 patients), hybrid and endovascular (11+59 patients). Result for hybrid approach is included in endovascular stent. Choice of approach is dictated by indication.	?	-	-
Bentham, 2013	UK	Case series	40		0%		Single center			
Chakrabati, 2009	UK	Case series	88		0%		Single center			
Chessa, 2005	Italy	Case series	71		1,5%		71 consecutive patients, 1 perioperative death.			
Forbes, 2007	USA	Case series	565		<0,5%		17 institutions. complications split by age group			
Krasemann, 2011	UK	Case series	68		0%		Single center			
Szkutnik, 2010	Poland	Case series	63		0%		Total of 247 procedures which of 63 included stent implantation.			

Project: Coarctation

Appendix 4:3

Outcome variable: Technical success; delivering a stent/surgery with acceptable result in the perioperative period

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n= Surg/endo	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Endovascular stent	Surgery				
Carr 2006	USA	Systematic review of case series	13 studies on primary stenting or angioplasty +stent 6 studies on surgery-	No information	98,7% ; n= 464 with primary stenting or angioplasty+stenting	100%, n= 213 surgical pts		-	-	-
Roselli 2012	USA	Cohort study	110	0	100% stent 100% hybrid	100% surgery	Stent n=59 Hybrid n=11 Surgery n=40 Mortality FU complete at median 56 months	?	-	-
Garcia 2010	Spain	Cohort study	11	0	100%, n=5	100%, n=6		?	-	-
Bentham 2013	UK	Case series	40	8	97,5% (1 stent embolization, no information on how it was handled)		Dropouts: 1 missing 1 death non-cardiac, 32/38 FU at 1 year. MR at 1 year. 20 native, 20 reCoA after surgery			
Chakrabarti 2010	UK	Case series	88 (54,5% adult)	4 pt, at 34 months	97,7% (1 pt aortic rupture requiring surgery, 1 pt aortic dissection))					
Chessa 2005	Italy	Case series	71 (59,1% adult)	0, at median FU 3,1years	97,2% (1death of aortic rupture in pt with re-CoA and aneurysm, stent and coils inserted. 1 repeated stent migration, procedure aborted)		2 more stent migrations noted, but no information on how they were handled. 52 native, 19 reCoA after surgery.			
Forbes 2007	USA	Case series Multi-center	565 (29,5% adult)	See comments	97,9% (1 death of aortic rupture, 2 aortic dissection requiring surgery)		Missing data in 23% to 53,1% of table data. 10,4% technical problems including balloon rupture, stent migration, where 90% were resolved without sequelae. 296 native, 228 reCoA after surgery, 21 post angioplasty, 20 post stent Complications split up by age group			

Project: Coarctation

Appendix 4:3

Outcome variable: Technical success; delivering a stent/surgery with acceptable result in the perioperative period

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n= Surg/endo	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Endovascular stent	Surgery				
Holzer 2010	USA	Case series Multi-center	302	See commen ts	96%		Age 2-63 years, mean 15. FU discharge 86% (260/302) FU>3 months 78% (115/147) FU>18 months 86% (43/50) 167 native, 135 reCoA			
Krasermann 2011	UK	Case series	68 (68% adult)	9	94% (4 pts with persistent invasive gradient > 20 mmHg)		41 native, 27 reCoA			
Szkutnik 2010	Poland	Case series	63	No informat ion	79,4% (5 pts suboptimal stent expansion)		Total material 203 patients, 110 native and 93 reCoA. Median age 15. 22,7% adult. The majority balloon angioplasty alone, 63 pts received stent			

Project: Coarctation
Appendix 4:4
Outcome variable: Hypertension at follow-up after coarctation repair

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention ENDOVASCULAR	Control OPEN SURGERY				
Tan 2005	UK	Cohort study	24 (13/11)	0	Pre-stenting: 145mmHg ± 20 Post-stenting: 129 ± 23 mmHg	Post-surgery 133 ± 21 mmHg Pre-surgery: no data	Systolic bloodpressure. No pre-surgery bloodpressure stated. Follow-up at 3-12 months, not separated per group. Additional definitions of hypertension are stated in the article	?	?	-
Bentham JR 2013	UK	Case series	40	6	0,8 before and 0,7 after stent placement		Number of hypertensive agents administrated before endovascular procedure and at latest follow-up, mean. Follow-up 1134 days mean			
Chakrabarti S 2010	UK	Case series	88	?	80,6% were hypertensive before stent placement, 68,2 % post procedure		Hypertension defined as requiring treatment. Median follow-up 34.5 months (range 4.2 - 72.8)			
Holzer R 2010	USA	Case series	302	0 0 155 252	43% hypertensive 59% hypertensive 45% hypertensive 32% hypertensive		Pre-procedural Pre-discharge >3 months post procedural >18 months post procedural Hypertension=requiring treatment Additional definitions of hypertension are stated in the article			
Krasemann T 2011	UK	Case series	68	2	40/68 (59%) patients were hypertensive before stent placement and 30/66 (45%) at latest follow-up		Hypertension= clinically hypertensive. Latest follow-up mean 41 months (range 6 days - 13 years) Additional definitions of hypertension are stated in the article			

Project: CoA endovascular vs surgery
 Appendix 4:5
 Outcome variable: Re-interventions

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Reinterventions Endovascular	Reinterventions Surgery				
Carr 2006	USA	Systematic review	Endo=633 Surg=213	?	65/633=10%	2/213=1%				
Garcia 2010	Spain	Cohort study	Endo=5 Surg=6	0	0	0				
Roselli 2012	USA	Cohort study	Endo=59 Surg=40	?	8/59=14%	5/40=12%	Hybrid approach excluded			
Chakrabarti 2010	UK	Case series	88 (54,5% adult)	4pt at 34 months	5,7%: 1 aortic rupture requiring surgery, 1 dissection, 1 aneurysm after stent fracture treated with stent, 2 intimal tears		Median FU 34,5 months. CT/MR in 96,5% 3-4 months post procedure			
Chessa 2005	Italy	Case series	Endo=71	0	4/71=6%					
Holzer 2010	USA	Registry	Endo=302		36/302=12%		6 pts had more than one reintervention			
Krasermann 2011	UK	Case series	Endo=68	9	26/68=38% 26/59=44%		40% had had previous intervention 5 pts had a third reintervention			
Szkutnik 2010	Poland	Case series	Endo=203	?	46/203=23%		93 pts had had previous intervention			
Bentham 2013	UK	Case series	Endo=40	?	5/40=12%		20 pts had had previous intervention			

Project: HTA CoA
 Appendix 4:6
 Outcome variable: other complications

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention	Control				
Carr 2006	USA	Systematic review	346 stent 213 surg		12 stent migration/embolization			-	-	-
Garcia 2010	Spain	Cohort study	11	0	1 intimal tear		The pt had pseudoaneurym before or due to intervention?	?	-	-
Bentham 2013	UK	Case series	40	8	1 stent embolization 1 late claudicatio		Dropouts 1 missing 1 death non-cardiac, 32/38 FU at 1 year. MR at 1 year.			
Chakrabarti 2010	UK	Case series	88	4 pt at 34 months	1 stent migration					
Chessa 2005	Italy	Case series	71 total 42 adult		2 stent migrations in 1 pt 2 stent migration					
Forbes 2007	USA	Case series, multicenter	565 total 167 adult		28 stent migration 13 balloon rupture		15% technical problems in age 20 and above, n=167. complications split by age group			
Holzer 2010	USA	Case series multicenter	302	See comments	1 balloon rupture(1/260) 9 stent migration (9/260) 2 stent fracture 3 months		Age 2-63 years. FU discharge 86% (260/302) FU>3 months 78% (115/147) FU>18 months 86% (43/50)			
Krasermann 2011	UK	Case series	68	9	2/68 balloon rupture 2/68 stent migration 2 repeat inflation					
Szkutnik 2010	Poland	Case series	203	?	1 stroke					

Author, year	Country	Study design	Number of patients n=	With draws - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention	Control				
Carr 2006	USA	Systematic review	13 studies on primary stenting or angioplasty +stent 6 studies on surgery-	No information	3%: 14 aneurysm, FU 34,8 months n= 464 with primary stenting or angioplasty+stenting	0 FU 7,8 years n= 213 surgical pts	No information on imaging techniques or frequency during FU	-	-	-
Garcia 2010	Spain	Cohort study	11	0	1 hemothorax in pt with pseudoaneurysm before or after intervention?	1 hemothorax without description of cause	FU mean 32,3 months post-stent (n=5) and 69,7 months post-surgery (n=6). MR or CT yearly in stented group only.	?	-	-
Chakrabarti 2010	UK	Case series	88 (54,5% adult)	4pt at 34 months	5,7%: 1 aortic rupture requiring surgery, 1 dissection, 1 aneurysm after stent fracture treated with stent, 2 intimal tears		Median FU 34,5 months. CT/MR in 96,5% 3-4 months post procedure			
Chessa 2005	Italy	Case series	71 (59,1% adult)	0, at median FU 3,1years	4,2%: 1 aortic rupture*, 2 aneurysm 1 year post-stent		Median FU 3,1 years *1 aortic rupture causing death in pt with reCoA and aneurysm who received stent and coils No information on imaging frequency.			
Forbes 2007	USA	Case series Multi-center	565 (29,5% adult)	See comments	4,1% (23/565): 1 death of aortic rupture, 3 aortic dissection requiring surgery, 5 dissections, 6 aneurysms, 8 intimal tears		Missing data in 23% to 53,1% of table data. No information on FU imaging frequency 296 native, 228 reCoA after surgery, 21 post angioplasty, 20 post stent complications split by age group			
Holzer 2010	USA	Case series Multi-center	302	See comments	1/260 dissection 1/260 aneurysm 2/115 aneurysm at FU>3 months		Age 2-63 years, mean 15. FU discharge 86% (260/302) FU>3 months 78% (115/147); 84% with imaging FU>18 months 86% (43/50); 92% with imaging 167 native, 135 reCoA			

Project: Coarctation
 Appendix 4:7
 Outcome variable: Aortic wall complications

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With draws - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention	Control				
Krasermann 2011	UK	Case series	68 (68% adult)	9	0% at initial stenting 7,7% (2/26) dissection at reintervention		Mean FU 41 months (6 days-13 years) CT/MR 3 months postop and on clinical judgement			
Szkutnik 2010	Poland	Case series	63	No information	1,6% 1/63: 1 dissection at balloon predilatation before stenting		Total material 203 patients, 110 native with 3,2 months FU and 93 reCoA with 4 months FU). No information on imaging at FU Median age 15. 22,7% adult. The majority balloon angioplasty alone, 63 pts received stent			

Project:Coartaction
 Appendix 4:8
 Outcome variable: Hospital stay

* + No problem
 ? Some problems
 - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention ENDOVASCULAR	Control OPEN SURGERY				
Roselli EE 2012	USA	Cohort	110 (59/11/40)	0	2,1 ± 2,5 (Hybrid; 9,4 ± 4,0)	9,6 ± 4,7	Length of stay in days (mean ± SD).	?	-	-
Garcia EM 2010	Spain	Cohort	11 (5/6)	0	7,8	11,83	Length of stay in days (mean). Length of stay in ICU also stated in article.	?	-	-

Appendix 5, Summary of Findings

High quality of evidence = ⊕⊕⊕⊕

Moderate quality of evidence = ⊕⊕⊕○

Low quality of evidence = ⊕⊕○○

Very low quality of evidence = ⊕○○○

Summary of Findings: Surgical or endovascular intervention for adult native, residual or re- aortic coarctation

Outcome variable Number of studies	Design	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Relative effect (95%CI)	Absolute effect	Quality of evidence GRADE
Long-term mortality 3 studies	1 SR of case series 2 cohort	Serious limitations ^d (-1)	No serious inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	?	Not relevant	-	0-3% endovasc 0-1% surgical	⊕○○○
Perioperative mortality 2 studies	2 cohort	Serious limitations ^d (-1)	No serious inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	?	Not relevant	-	0 in both groups	⊕○○○
Technical success 3 studies	1 SR of case series 2 cohort	Serious limitations ^d (-1)	No serious inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	?	Not relevant	-	98.7-100% in endovasc 10% in surgical	⊕○○○
Hypertension 1 study	Cohort	Serious limitations ^d (-1)	No serious inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	Unlikely	Not relevant	-	129+-23 mm Hg in endovasc 133+-21 in surgery	⊕○○○
Hospital stay 2 studies	Cohort	Serious limitations ^d (-1)	No serious inconsistency	Serious indirectness (-1)	No imprecision	?	Not relevant	-	2.1-7.8 days in endovasc 9.6-11.8 in surgery	⊕○○○
Re-interventions	1 SR of case series 2 cohort	Serious limitations ^d (-1)	No serious inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	?	Not relevant	-	10-14% in endovascular 1-12% in surgical	⊕○○○

Appendix 5, Summary of Findings

High quality of evidence = ⊕⊕⊕⊕

Moderate quality of evidence = ⊕⊕⊕○

Low quality of evidence = ⊕⊕○○

Very low quality of evidence = ⊕○○○

Summary of Findings: Surgical or endovascular intervention for adult native, residual or re- aortic coarctation

Outcome variable	Design	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Relative effect (95%CI)	Absolute effect	Quality of evidence GRADE
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Aortic wall complications	1 SR of case series 1 cohort	Serious limitations ^d (-1)	No serious inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	?	Not relevant		In SR 3% in endovasc, 0 in surgery, 1/6 vs 1/5 in cohort study	⊕○○○
Other complications	1 SR of case series, 1 cohort	Serious limitations ^d (-1)	No serious inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	?	Not relevant		3.5% in SR in endovasc, 0 for surgery, in cohort 1/5 in endovasc, 0 in surgery	⊕○○○

^d. Patient groups not comparable
No longterm follow up
Few events

Region Västra Götaland, HTA-centrum

Health Technology Assessment
Regional activity-based HTA



HTA

Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the quality of evidence the Centre of Health Technology Assessment in Region Västra Götaland is currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High quality of evidence	= (GRADE ⊕⊕⊕⊕)
Moderate quality of evidence	= (GRADE ⊕⊕⊕○)
Low quality of evidence	= (GRADE ⊕⊕○○)
Very low quality of evidence	= (GRADE ⊕○○○)

In GRADE there is also a system to rate the strength of recommendation of a technology as either “strong” or “weak”. This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

Christina Bergh, Professor, MD.
Head of HTA-centrum

