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CURRENT OPINION

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Transcatheter adult congenital heart disease interventions: organization of care – recommendations from a Joint Working Group of the European Society of Cardiology (ESC), European Association of Pediatric and Congenital Cardiology (AEPC), and the European Association of Percutaneous Cardiac Intervention (EAPCI)

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Introduction

The improvement in survival of operated patients with CHD (congenital heart disease), has led to an increasing number of adult patients with CHD (ACHD) in particular those with more complex disease.[1–5] There is general agreement that ACHD patients have special needs and therefore physicians responsible for their care need specific training and expertise.[1–11]

The European Society of Cardiology (ESC) has published practice guidelines for the management of grown-up congenital heart disease (GUCH),[1] and more recently the GUCH-ESC Working Group published a position paper making recommendations for the standards and organization of care for ACHD, as well as recommendations for training in ACHD within Europe.[2] However, that document did not include recommendations on trans-catheter interventions. There are many issues including where interventions should be delivered on a national scale, and how to train, develop and maintain the appropriate competencies to be recognized as an ACHD interventionist.

This publication is a position paper from a joint ESC GUCH WG, the European Association of Pediatric and Congenital Cardiology (AEPC) ACHD and Intervention WG's, and the European Association of Percutaneous Cardiac Intervention (EAPCI), aimed at addressing these issues. These recommendations are based both on published evidence and a consensus of experienced practitioners in the care of adult CHD patients along with paediatric and adult interventionalists.[12–17] Interventional treatment of arrhythmia in ACHD is not addressed within these recommendations.

Where should ACHD catheter interventional procedures be performed on a national scale?

Catheter-based interventions, either as stand-alone or hybrid procedures, are an appealing alternative to conventional open-heart surgery, obviating the need for reoperation, and cardiopulmonary bypass[18] (*Table 1*). It is highly likely that, as reported for patients operated upon by surgeons,[19,20] transcatheter interventions in the ACHD population are managed better by operators skilled in the care of CHD lesions. It is of particular importance that a programme performing trans-catheter interventions in ACHD patients should be co-located with appropriate cardiac surgical services for the management of procedural complications. In many programs experienced paediatric interventional cardiologists form an important component

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of ACHD intervention services but in others (for example those based in a separate childrens hospitals) paediatric interventionalists may be uncomfortable with the interventional management of adults with congenital cardiac problems and there may be full separation of services.

Concentration of ACHD specialist care in a limited number of designated centres allows quality assurance as well as co-location of key services. Institutional requirements for ACHD centres have been already published.[2] The majority of established units caring for ACHD patients will offer interventional treatment at some level. Descriptions of the service and training requirements are important for safety due to the breadth and complexity of ACHD intervention. We propose a classification in Level 1 and Level 2 centres performing ACHD-Intervention (*Tables 2* and *3*). It is recognized that in an early phase of development, or during a period of re-organization, fewer cases might be performed in a particular centre, but a programme should reach the minimum level of activity relevant to the case-mix proposed within 3 years of starting (*Table 4*). If the case load cannot be achieved within that centre, then operators should be prepared to work at more than one site in order to maintain quality and fulfil governance arrangements. It is accepted that the population of different countries in Europe vary as do the logistic arrangements for the care of ACHD patients however the quoted numbers may act as a guide for the organization of a nationwide network of ACHD-interventional units. All institutions should have in place a policy for the introduction of 'new' or 'novel' procedures including arrangements for patient consent and governance.

Table 1 List of ACHD interventional procedures

1. Closure of patent ductus arteriosus
2. Closure of simple atrial septal defects (II ASD and PFO)
3. Closure of complex atrial septal defects (II ASD and PFO)
4. Closure of native muscular or perimembranous, as well as acquired ventricular septal defects (VSDs) (e.g. residual-patch VSDs, post-infarction, and even post-traumatic VSD)
5. Closure of coronary fistulas, pulmonary vascular malformations and aorto-pulmonary collaterals, and veno-venous collaterals
6. Angioplasty and stenting of pulmonary artery
7. Angioplasty and stenting for coarctation of the aorta
8. Angioplasty and stenting of pulmonary veins
9. Angioplasty and stenting of surgical conduits, and baffles
10. Angioplasty and stenting of interatrial septum and Fontan fenestrations
11. Transcatheter pulmonary valve implantation (TPVI)
12. Transcatheter pulmonary valve-in-valve implantation
13. Transcatheter tricuspid valve-in-valve implantation
14. Closure of paravalvular leaks
15. Recanalization of obstructed vessels or valves
16. Hybrid ACHD procedures in a dedicated hybrid suite

Training and standards for recognition as an Adult Congenital Heart Disease interventionist

At the present time, the training indications for physicians seeking to perform ACHD interventions remain unclear and underdeveloped.[14] We suggest that ACHD interventional care must be delivered by people who either are trained as CHD or ACHD caregivers, and are part of an ACHD care centre (as recognized by existing nationale and international guidelines and accreditation policies), where individual procedures are reviewed, and discussed within a multidisciplinary team. A Trainee should undergo a minimum period of 12 months supervised by an experienced operator within a Level 1 Center before carrying out an unsupervised ACHD intervention. Several national and international societies have published consensus papers on case numbers in specific interventions to achieve a level of expertise for trainees in CHD interventions.[20,21] Setting clear numbers for trainees in this field can be problematic as different operators learn at different speeds. We suggest that a mix of volume-procedure and some specific objectives should be better considered.[11–13] It is appropriate for supervisors to determine, based on competence rather than absolute numbers, whether individual operators have reached a level where they can operate independently.

The specific objectives to be achieved during the training are[11–13]:

(1) A full understanding of the anatomical defects concerned, the natural history of treated and untreated structural congenital abnormalities or residua, and related pathophysiology.
(2) Knowledge and understanding of both the indications and contra-indications for interventions in ACHD patients.
(3) Knowledge of the specific techniques and interpretation of the results of imaging (including 3D modalities/computed tomography/magnetic resonance imaging).
(4) Familiarity with the full range of equipment necessary for the interventional procedures undertaken in ACHD patients.
(5) Knowledge of the techniques to perform an accurate vessel access, as well as some atypical access like transhepatic; the use of Doppler to help a difficult access should be taken into consideration.
(6) Demonstration of appropriate dexterity and the ability to 'navigate' through a case focusing on the objectives and maintaining patient safety.
(7) Ability to manage complications, and adjunctive treatment including the use of retrieval devices.
(8) Development of communication skills, specifically an ability to correctly and thoroughly obtain informed consent. Good communication skills including appropriate sensitivity and understanding are essential.
(9) An understanding of how to manage vulnerable young adults in particular those unable to give informed consent
(10) Ability to work in a team, particularly within an MDT format.
(11) Continuous activity of the trainee over the training period.

The trainee should take part in the process of counselling leading to informed consent from the patient, or their legal guardians. The trainee must be involved in discussion and subsequent debrief of case

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Table 2 **Requirements for Level 1 centre**

	Infrastructure	Expertise
Imaging modalities	Doppler for vascular access, echocardiography including transoesophageal, intracardiac and contrast echocardiography and 3D echo modalities, CT, MRI	Evaluation pre- and post- and support all interventional procedures
Catheterization laboratory	Preferably biplane fluoroscopic and digital imaging provisions (3D angio rotational software, fusion imaging modalities are suggested but not mandatory); comprehensive haemodynamic monitoring, recording and data storage equipment Stock of materials/devices for emergency procedures, should be available Access to a dedicated hybrid suite At least two operators specialized in ACHD-interventions. Specialized Nurses team is suggested, but not mandatory	All procedures should be done (*Table 1*) Complication management and bail-out procedures Continuously available interventional service 24/7
Pediatric/congenital heart surgery programme	On site congenital cardio-thoracic surgeon and associated team (anaesthesiologists and intensivists)	Surgical complication management in emergency situations (tamponade, vessel rupture, extracorporeal circulatory support)Availability 24/7
Inpatient and outpatient facilities	Approved ACHD-clinicians	Knowledge on indicating interventional strategies and long-term follow-up management
Multidisciplinary team conferences	Regular meetings involving ACHD-clinicians, experienced imagers, ACHD-interventionist, and congenital cardiac surgeons	Discussions to appropriately prepare a case, as well as morbidity and mortality assessments after an ACHD-intervention
Quality assessment	Institutional audit and quality management programme	Transparent availability of institutional results for interventions to national health authorities and ACHD patient associations where applicable
Education and training	ACHD-interventional training programme	Covering the whole spectrum of procedures providing educational resources and mentorship
Research	Research facilities	Possibilities to study the unique haemodynamic changes following cath interventions for CHD and lead trial for new techniques/devices

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Table 3 Requirements for Level 2 centre

	Infrastructure	Expertise
Catheterization laboratory	Mono or biplane fluoroscopic; comprehensive haemodynamic monitoring, recording and data storage equipment	A limited subset of interventions with less complexity on a high level of expertise
	At least one operator specialized on ACHD-interventions	Supportive collaborations with interventional cardiologists and cardiac surgeons
Pediatric/congenital heart surgery programme	On site congenital cardio-thoracic surgeon	Surgical complication management in emergency situations (tamponade, vessel rupture, and extracorporeal circulatory support)
Multidisciplinary team conferences and training	Regular meetings between ACHD-interventionists of Level 2 and Level 1 centres	Discussions to appropriately prepare a case, as well as morbidity and mortality assessments on a regular basis seem useful for further training and shared
Quality assessment	Institutional audit and quality management programme	Transparent availability of institutional results for interventions to national health authorities and ACHD patient associations

Table 4 Institutional volumes in established centres performing ACHD-interventions on different level of care

Annual numbers of interventions by operators	Level 1 centre	Level 2 centre
Lead interventionalist	≥70—full range of interventions At least: ≥10 PPVI ≥10 angioplasty and stenting for CoA, PA, surgical conduits, and baffles	≥30—selected subset of interventions (PFO, simple ASD, PDA, pulmonary vascular malformations, aorto-pulmonary collaterals, and veno-venous collaterals)
Second operator	≥30—full range of interventions	≥30—including joint interventions for the selected subset
Total volume (including joint interventions)	≥100—full range of interventions	≥60—selected subset of interventions

strategy, and following the procedure should be taught collation, and discussion of haemodynamics and angiographic data before eventually performing this independently. Monitoring for post-procedural complications and discharge planning should be coordinated by the trainee and discussed with the supervisor[11–13] (*Table 5*). For particularly difficult cases an external experienced proctor may be required and should be encouraged and supported by the institution.

Accreditation and certification of an individual ACHD-interventionalist remains, in our opinion the responsibility of a Level 1 centre, according with the specific national accreditation policies A European (ESC-EAPCI-AEPC) joint certification for practitioners in this area is an aim.

Trainers should be experienced congenital interventionalists working within a Level 1 Center ideally with an interest in education and documented skills in training and assessment of those in training, particularly in this environment. Training of this nature is a life-long process and trainers would generally be expected to act in a 'mentorship' role for younger interventionalists once training is completed.

Review of recommendations

Interventions in Adult Congenital Heart Disease patients are an evolving discipline and new data are emerging at a rapid pace. Therefore, these recommendations will be reviewed and adjusted in every 4 years.

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Table 5 Required competencies for single procedure

Knowledge base	
1. Natural history, medical management and guidelines	
2. Image interpretation (echo, MRI, CT scan) pre and during the procedure	
3 Indications to intervene	
4. Optimal percutaneous access	
5. Sheaths, orientable sheaths, wires, and catheters to use	
6. Occlusive devices, stents and balloons	
7. Acute and long-term post-procedural care	
8. Managing complications (vascular occlusion, dissections, thromboembolisms, haemodynamic collapse, drainage of pericardial effusion, retroperitoneal bleeds, cardiac perforations/tamponade, arrhythmias/heart blocks, coronary occlusions, etc.)	
Procedure	**Interventional specific skills**
PFO closure	Retrieval of embolized devices
ASD closure	When and how to use sizing balloons
	Closure in patients with PAH and/or AF/left heart disease
	Retrieval of embolized devices
PDA closure	Crossing the PDA (anterograde and retrograde)
	Closure in patients with PAH
	Retrieval of embolized devices
Pulmonary valvuloplasty	Selection of adequate balloon sizes/wires
VSD (native or post-operative) closure	Management in patients with PAH
Closure of coronary fistulas, pulmonary vascular malformations, veno-venouscollaterals, and aorto-pulmonary collaterals	How to access feeder vessels (antegrade and retrograde) How to manage coronary complications (a cooperation with Adults Cardiology Interventionists is recommended)
Angioplasty and stenting of pulmonary artery branch stenosis	Use of large stents and stenting techniques
Angioplasty and stenting for coarctation of the aorta	Use of large stents, covered stents, and stenting techniques
Angioplasty and stenting of pulmonary veins	Trans-septal puncture
	How to access and image the each of the four pulmonary veins
Angioplasty and stenting of surgical conduits, baffles and homograft	Interpreting haemodynamics of complex CHD in the Cath lab Stenting techniques
Angioplasty and stenting of interatrial septum and Fontan fenestrations	Interpreting haemodynamics of single-ventricle physiology in the Cath lab Trans-septal puncture or conduit perforation
Percutaneous pulmonary valve implantation (PPVI)	Use of PPVI devices
	How to assess the size of the PA trunk and landing zone
	How to assess coronary arteries during balloon inflation
	How to retrieve a ruptured balloon
	How to retrieve an embolized stent or a percutaneous valve
	How to treat a conduit rupture
	How to do a Valve-in-Valve procedure
	How to manage closure of large vessel access
Percutaneous tricuspid valve-in-valve intervention	Knowledge of the characteristics of the surgical valves
	How to choose the percutaneous valve (Type and size)
	How to retrieve a ruptured balloon
	How to retrieve an embolized stent or a percutaneous valve
	How to manage closure of large vessel access
Percutaneous paravalvular leak	Interpreting 3D echo images, haemodynamics of different leaks in the Cath lab
	Assessing coronary perfusion

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