Position Statement

Position statement on contraceptives in patients with congenital heart disease

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ABSTRACT

The increase in survival rates among patients with congenital heart disease (CHD) has introduced new challenges that require the involvement of adult cardiologists. Most women of reproductive age with CHD are sexually active, making the evaluation and counseling on contraceptive method (CM) choice an essential practice in cardiology.

Unfortunately, less than half of women with CHD received counseling prior to their first sexual activity. Given the prevalence of sexual activity and the risk of unplanned pregnancy in adolescents and young adults with CHD, contraception and pregnancy counseling should begin during adolescence in consultations with the pediatric cardiologist and continue with the adult cardiologist.

INTRODUCTION

CWhy is it important to question and educate on contraceptive methods from cardiological consultations?

Unintended pregnancies in women with congenital heart diseases (CHD) could be potentially dangerous and harmful for the health both of mother and fetus.[1,2,3] Many patients with CHD in a reproductive age are under treatment with potentially teratogenic medication, such as angiotensin-converting enzyme inhibitors, vitamin K antagonists, and so on.[4,5]

For this reason, we should encourage women to develop reproductive goals with cardiologists, obstetricians and family doctors, to design family planning and reduce as much as possible the risks of morbimortality associated to pregnancy.

Instructing on contraception is extremely important for women classified as mWHO III and IV, as pregnancy entails a very high risk in those with conditions classified as mWHO class III, and it should be avoided in class IV *(Table 1)*.[5,6]

What contraception methods are available?

Contraception eligibility is based on the risk of failure in terms of contraception and the risk of developing secondary effects in women.

Through the medical criteria of eligibility for the use of contraception, the World Health Organization (WHO) proposes categories based on evidence in terms of the conditions in which an individual can use contraception methods safely.[7,8]

There are 4 categories:

- **Category 1:** a condition where there are no restrictions for contraception.
- **Category 2:** a condition where, in general, the advantages of using the method exceed the theoretical or verified risks.
- **Category 3:** a condition where, in general, the theoretical or verified risks exceed the advantages of using contraception.
- **Category 4:** a condition representing an inadmissible health risk if contraception is used.

The aim of this position statement is selecting the most appropriate contraception method in patients with CHD, mainly in those in categories 3 and 4.

Available contraception currently is:[7]

- Barrier methods
- Combined hormonal contraception (CHC)
- Progestogen-only contraceptives
- Emergency contraception
- Intrauterine devices (IUD) with levonorgestrel or copper
- Diaphragms
- Surgical

These methods according to the rate of failure they present will be divided in different groups: level 1, 2 and 3.

Level 1 are those with less than 1% of failure, including: dermal implants, intrauterine devices and surgical sterilization. Level 2 have 6-12% of failure rate, including:

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TABLE 1.
Classification of maternal cardiovascular risk according to the modified World Health Organization (mWHO)

mWHO classification	Diagnosis (when clinical state is stable)	Riesgo asociado al embarazo	Tasa de eventos cardíacos maternos	Recomendación / Asesoramiento
mWHO I	• pulmonary valve stenosis • patent ductus arteriosus • mitral valve prolapse • simple lesions repaired (ASD, VSD, ductus, anomalous pulmonary venous drainage) • isolated ectopic beats	No detectable increase in maternal mortality risk, and no or mild morbidity increase	2.5–5.0%	Indicated advice
mWHO II	• non-operated ASD or VSD • tetralogy of Fallot repaired • supraventricular arrhythmias • Turner syndrome with no aortic dilatation • mild LV dysfunction (EF >45%) • hypertrophic cardiomyopathy • mild or moderate valvulopathy • Marfan or HTAD with no aortic dilatation • aorta < 45 mm (bicuspid valve) • repaired coarctation	Mild to moderate increase in morbidity risk / small increase in risk of mortality	5.7–10.5%	Indicated advice
mWHO II–III	• atrioventricular septum defect • moderate LV dysfunction (EF 30–45%) • previous peripartum cardiomyopathy with no residual dysfunction • mechanical valve prosthesis • systemic right ventricle with normal or mildly depressed function • Fontan circulation with no complications	Intermediate risk of maternal mortality or moderate to severe morbidity	10–19%	Indicated advice
mWHO III	• not repaired cyanotic heart disease • complex congenital heart diseases • moderate mitral valve stenosis • asymptomatic severe aortic valve stenosis • moderate aortic dilatation • ventricular tachycardia	High risk of maternal mortality or severe morbidity	19–27%	Expert advice is required
mWHO IV	• pulmonary hypertension • severe LV dysfunction (EF <30% or NYHA III–IV) • peripartum cardiomyopathy with residual dysfunction • severe mitral valve stenosis • symptomatic severe aortic valve stenosis • systemic right ventricle with moderate or severe dysfunction • severe aortic dilatation • vascular Ehlers-Danlos syndrome • severe recoarctation • complicated Fontan circulation	Extremely high risk of maternal mortality or severe morbidity	40–100%	Contraindicated pregnancy; consider interruption if it occurs

combined estradiol-progestogen pills, progestogen pills, dermal patches, vaginal ring and diaphragms. Level 3 are those with highest rate of failures, represented by barrier methods and spermicides *(Figure 1)*.[1]

The choice of contraception should be individual according to the underlying lesion in the patient, risks, efficacy of the method by level and duration.

Barrier methods, coitus interrupts or withdrawal, and the calendar method have a high rate of level 3 failure, so they are not recommended.

In a recent study, carried out by the Hospital Universitario Vall d'Hebron, it was found that at the time of consultation, 25.8% of women with CHD were not using contraception, while 46.4% used level 3 methods, 21.8% level 2 and just 5.8% level 1. After follow-up by a joint consultation with gynecology and cardiology services, distribution was the following: 25% were not using any contraception, 22.8% continued using level 3, 34.6% level 2 and 17.6% level 1. These changes turned out to be statistically significant ($p<0.001$).[9]

- **Combined hormonal contraception**

The estrogen component increases the risk of venous thromboembolism (VTE) and it is known that it increases

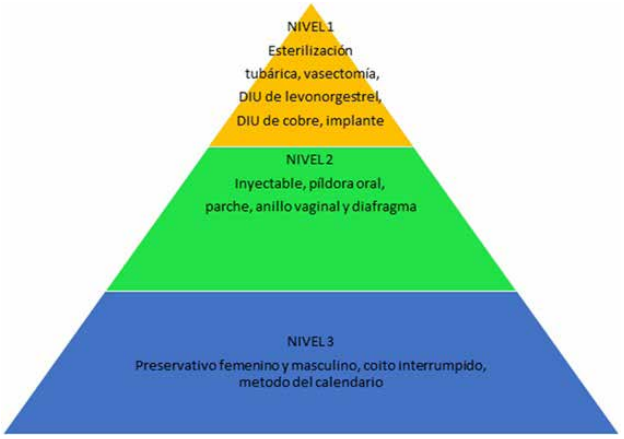


FIGURE 1.
Classification of contraception methods according to the failure rate they present

blood pressure, so it is not advised in patients with preexisting heart disease or hypertension (HTN).[3]

The absolute risk of TVE in women not using CHC is 0.19 to 0.37 per 1000 women/year; while in those using it is 0.55 to 1.41 per 1000 women/year, with a greater risk among users of third- and fourth-generation progestins (desogestrel and gestodene), in comparison with second-generation ones (levonorgestrel or norgestrel).[10] CHCs are associated to an increase of 2-6 times in risk in comparison with the baseline.[11]

Evidence showed that CHC with the same dose of estrogen but different progestins were associated to different VTE risks. It was suggested that the progestin component could play a role in the development of thrombosis. However, given that progestogen-only contraception does not interfere with coagulation protein synthesis, the difference in VTE risk specific to each CHC could only be attributed to a distinctive modulation of the procoagulant effect of ethinylestradiol (EE), exercised by progestins.[12]

Paradoxical embolism is a significant entity between patients with VTE and intracardiac shunts such as atrial septal defect (ASD), ventricular septal defect (VSD) and patent foramen ovale (PFO). Although clinical presentation is very diverse, it may endanger life.[13]

The prevalence of stroke in patients with CHD is higher when compared with healthy people with the same age.[14] Patients with transposition of the great arteries (TGA) with atrial switch present a high prevalence of remaining shunts between the new atria; patients with Ebstein anomaly have a prevalence of ASD/PFO of 80-90%; patients with pulmonary and/or tricuspid regurgitation, at least moderate, may manifest the presence of PFO with right-left shunt in exercise, among others.[5]

On the other hand, most patients required at least one catheterization in childhood, so they present a higher likelihood of chronic venous insufficiency and VTE when exposed to CHC.[15]

It is important to highlight that heart failure is a frequent complication, present in 20-50% of the population with CHD. History of hospital admission due to heart failure and/or atrial flutter or fibrillation in the last three months presents an odds ratio of more than 10 to predict VTE events.[5,11]

Because of what has been presented here, this Committee recommends not using CHC in patients with high probabilities of presenting atrial septal defect or patent foramen ovale in any of their forms, even when they are not detected by echocardiogram. Likewise, it is suggested to avoid using them in patients with heart failure or atrial arrhythmias.

Furthermore, we consider that using CHC should be avoided in patients with a higher risk of developing hypertension due to their base pathology, as in the case of coarctation of the aorta.

• What patients with CHD can use CHC?

1. Patients with no intracardiac shunt
2. Patients with no heart failure
3. Patients with no hypertension
4. Patients with no history of embolic events.

• Progestogen-only contraception (POC)

POCs are a more secure option for the previously mentioned patients, as they decrease the risk of complications proper of the estrogen component and maintain a level 1 failure rate.[7]

POCs act by thickening cervical mucus, thus preventing the penetration of sperm and reducing endometrial receptivity, making implantation impossible. The mechanism of action depends on the method used (IUD, contraception pills, implants).[3,7]

Oral POCs may contain levonorgestrel (LNG), norethisterone acetate or desogestrel, and traditionally, they have been associated to strict timetable rules for their ingestion, particularly for the LNG formulation, whose time variation allowed is 3 hours, and the strict consumption of delayed or forgotten pills demands a high level of discipline by patients.[16]

The most common progesterone contraception is the one with the highest dose: desogestrel 75 micrograms, which is more reliable as it inhibits ovulation. Its contraceptive efficacy is similar to that of CHC and is safe for women with congenital heart disease.[3,8]

The most frequently reported secondary effect by patients in treatment with any of the POCs was irregular bleeding. Considering the high percentage of patients receiving antiplatelet drugs or anticoagulants, this was the main reason for dropping POCs. In most patients, bleeding happens at the onset and then it disappears.[9]

Drospirenone in a 4 mg dose in a 24/4 administration regimen provides an efficient contraception, with a good safety profile and tolerability in a wide range of women, including those with overweight or obesity, and it is an op-

tion for most women, regardless of blood pressure, body mass index or thromboembolic risks. In comparison with desogestrel, it presents a lower rate of bleeding.[17,18]

Depot medroxyprogesterone acetate can be administered by intramuscular injections every three months.[3]

Subdermal implants containing levonorgestrel or etonogestrel are another option that maintains contraceptive efficacy for 3 to 5 years, and are efficient and safe reversible contraception methods for women with CHD.[15]

Emergency contraception can be used in patients with CHD with no problems, although patients should be trained so that this is not an option due to the risk of unintended pregnancies in classes III and IV of the WHO. They contain LNG in 1.5 milligrams doses.[19]

We consider that POCs are a safe option for patients with intracardiac shunt, heart failure and hypertension.

• Intrauterine devices

The two usual types of reversible intrauterine devices are copper IUD, with an average duration of 10 years, and the one that releases LNG, known as intrauterine system (IUS), with an average duration of 5 years.

IUS is one of the most efficient and safe contraception methods. IUS offers other non-contraceptive benefits, such as reduction of heavy menstrual bleeding, iron deficiency anemia, pelvic pain (particularly in women with endometriosis), and prevention of endometrial hyperplasia, in comparison with copper IUS. No prophylaxis is required against infectious endocarditis for the insertion of these devices.[3,7]

In patients with anemia, reduction of menstrual bleeding could be beneficial, just as in people with valve prosthesis or atrial arrhythmias requiring anticoagulation.

IUS can be inserted in outpatient care with local anesthesia; however, in patients with Eisenmenger syndrome, Fontan-Kreutzer procedure, preexisting arrhythmias or ventricular dysfunction, insertion in a hospital environment is advisable due to the risk of vasovagal reaction during the procedure.[9,15,19]

Currently, there are two IUS available, the Mirena® and the Kyleena®, which vary in the LNG dose they contain.

A combination of barrier contraceptives for STD prevention and LNG IUS is ideal.

• Surgery

In group IV women with Eisenmenger syndrome or CHD with pulmonary hypertension, laparoscopic or minilaparotomy tubal ligation can be considered as a permanent contraceptive method, assuming the anesthetic risk. As alternative, vasectomy may be considered for the partner.[3,7,9]

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