Indication

Carvedilol is a non-selective beta blocker with alpha blocking action. The beta blocking action reduces heart rate and cardiac contractility by blocking the action of catecholamine on the heart muscle, while alpha blocking action causes peripheral dilatation by blocking the action of catecholamine on the peripheral arteries and arterioles.

Catecholamine levels are increased in patients with dilated cardiomyopathy and heart failure, and this appears to have a deleterious effect on the heart muscle. There are few studies in children, but adults with dilated cardiomyopathy (heart muscle failure) benefit from carvedilol with an increase in heart muscle function, improved well-being, and increased lifespan. The cause of this improvement is uncertain but probably relates to a reduction in heart rate, remodelling of the heart muscle subsequent to blocking the deleterious effect of catecholamine “over-stimulation”, and afterload reduction secondary to peripheral vasodilation. It may take 4 to 6 months for these positive changes to occur.

The short term effects of beta blockade in patients with heart failure are quite the reverse. The decrease in heart muscle contractility can make patients feel fatigued and unwell, and can cause severe hypotension. For this reason the medication is started in a very small dose and increased gradually. If the patient experiences side effects then the dose is reduced to the previous level and increased at a smaller increment - side effects tend to be associated with the magnitude of dose increase rather than the absolute dose.

Carvedilol is used in children with dilated cardiomyopathy after discussion with consultant paediatric cardiologist.

Pharmacokinetics

Elimination half life
Children < 3.5 years = 2.2 hours.
Children over 3.5 years = 3.6 hours
Adults = 5.2 hours.
Elimination processes dependent on hepatic blood flow

Absorption time - between 0.5-2.5 hours
CARVEDILOL – ADMINISTRATION IN INFANTS & CHILDREN

Dose

- Initial dose 0.05mg/kg/dose twice daily.
- Increase every two weeks by 0.05 mg/kg/dose for the first increment then by 0.1 mg/kg/dose for the next increment, aiming for a maintenance dose of 0.35mg/kg/dose given twice daily (not more than 25mg twice daily).
- Admit for observation to Day Stay or the ward for initiation and at each dose increment increase (in consultation with Cardiologist).

If side-effects occur the dose should be increased at longer intervals and by smaller increments.

Side Effects

- Common - Dizziness, hypotension, headache, bradycardia
- Less common – Vomiting, orthostasis, tiredness, dyspnea, edema

Contraindications

Absolute: History of asthma
Relative: Severe congestive heart failure unresponsive to diuretic and ACE inhibitor

Administration of First Dose

The “First dose” of Carvedilol may be given in day stay area, or following admission to the ward. The venue (ward vs. day stay) must be discussed with the paediatric cardiologist and will be dependant on the child’s age, and morbidity and the availability of nursing staff for monitoring.

The following must be completed before the first dose is given:

- Nursing and medical admission completed
- Resuscitation sheet in patient’s notes and emergency equipment at bedside
- Family are aware of reason for admission and importance of staying on the ward after medicine given
- Baseline observations taken (Heart rate, Respiratory rate, Blood pressure, temperature and Oxygen saturations if required)
- Carvedilol dose is clearly charted on Drug Administration sheet with BP parameters clearly documented by medical staff
Observations after First Dose

There is potential for profound hypotension or shock

- Ensure BP is within acceptable range before administration
- Check BP and Heart rate every 30 minutes for at least 4 hours or until stable.
- Notify medical staff of a significant drop in Systolic and Mean BP (usually >20mmHg from base line)
- Notify medical staff urgently if child is symptomatic (e.g. dizzy, pale, altered level of consciousness, profoundly hypotensive/ bradycardic, tachycardia, capillary refill > 3 seconds, cool peripheries)

Prescribing Carvedilol for Outpatient Use

- Contact Ward Pharmacist as soon as it is confirmed that the child will go home on carvedilol oral liquid.
- For the oral liquid carvedilol formulation an HEC (Hospital Exceptional Circumstances) application is required. The ward pharmacist can help complete this form.
- Once HEC is completed and faxed to Pharmac, send or fax a script to Level 5 Pharmacy (Outpatient Pharmacy) with an SO12.
- On-going supplies of oral liquid carvedilol can only be obtained from a hospital pharmacy once the HEC has been approved.
- For children from areas outside Auckland who need oral liquid carvedilol contact the ward pharmacist so that arrangements can be made with the appropriate hospital pharmacy.
- Ensure family are aware to refill carvedilol prescription early (don’t let oral suspension run out) – as there can be delays in getting refills.
Carvedilol Administration in Infants & Children Page: 4 of 6

Discharge Planning and Family education

- Pharmacist informed of ALL children who are commenced / and discharged on Carvedilol.
- Family / Caregiver discharged with clear instruction for medication administration.
- Family / Caregiver has demonstrated competence in drawing up appropriate dose of Carvedilol.
- Family / Caregiver educated on medication purpose, administration, storage (safety) and side effects – medication information pamphlet given to caregiver.
- Family / Caregiver aware of common side effects (dizziness / feeling faint, headache) and less common side effects (nausea and vomiting, orthostasis, tiredness, dyspnoea, oedema). Know to contact PCCS service if child experiencing these side effects.
- Family / Caregiver aware of action to take if side effects life threatening – profound hypotension or signs of shock – call 111
- Family / Caregiver given medical discharge letter AND is aware of follow up arrangements at the Cardiology clinic

Dose increases

- Child to be managed in Cardiology clinic as a Day Stay patient
- Some children may be required to be admitted to the ward with every increase in Carvedilol dosage.

Management and observations - as with “First dose” of Carvedilol

- Resuscitation sheet in patient’s notes and emergency equipment available
- Child reviewed by Nursing and medical team prior to the administration of the increased dose of Carvedilol
- Baseline observations taken - ensure BP within acceptable range
- Family are aware of the importance of staying in Day stay after increased dose of carvedilol given
- Carvedilol dose is clearly charted on Drug Administration sheet with BP parameters clearly documented by medical staff
- Check BP and Heart rate every 30 mins for a minimum of 4 hours or until stable.
- Notify medical staff of a significant drop in Systolic and Mean BP (usually >20mmHg from base line) or if child symptomatic
CARVEDILOL – ADMINISTRATION IN INFANTS & CHILDREN

Discharge after Dose increase

- Child must stay for a minimum of 4 hours observation in day stay clinic following administration of increased dose of Carvedilol
- ½ hourly observations for 4 hours are within acceptable parameters
- Child must be reviewed by medical officer before discharge from day stay clinic
- Family have appropriate script and have clear instruction for the increased medication administration
- Family / Caregiver has demonstrated competence in drawing up appropriate (increased) dose of Carvedilol
- Family / Caregiver aware of common side effects and know to contact PCCS service if child experiencing these side effects.

References


Buck ML. Use of Carvedilol in Children With Cardiac Failure. Pediatr Pharm. 2005;11(2)
Appendix – Quick Reference Guide

Guidelines for Carvedilol Administration
In Infants and Children

**Description**
Carvedilol is a nonselective beta blocker that also has alpha blocker and antioxidant effects.

**Background**
- Carvedilol has been shown to be beneficial in adults and children with dilated cardiomyopathy.
- Studies in adults have shown reduced symptoms of heart failure, a reduction in the rate of progression of heart failure, improved left ventricular function, and improved survival.
- Studies in children have shown improved symptoms of heart failure, and improved left ventricular function.

**Indication**
- Dilated cardiomyopathy after discussion with a consultant paediatric cardiologist

**DOSE**
- Initial dose 0.05mg/kg/dose twice daily.
- Increase every two weeks by 0.05 mg/kg/dose for the first increment than by 0.1 mg/kg/dose for the next increment, aiming for a maintenance dose of 0.35mg/kg/dose given twice daily (not more than 25mg twice daily).
- Admit to Day stay or ward for initiation and dose increments.

If side-effects occur dose should be increased at longer intervals and by smaller increments.

**Side Effects**
- Common - Dizziness, hypotension, headache, bradycardia
- Less common – Vomiting, orthostasis, fatigue, dyspnea, edema

**CONTRAINDICATIONS**
- **Absolute**
  - History of asthma
- **Relative**
  - Severe congestive heart failure unresponsive to diuretic and ACE inhibitor

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