amiODARONe
Newborn use only

2023

Alert	Only administer upon the advice by cardiology team. Only administer where facilities exist for cardiac monitoring and defibrillation. Intravenous formulation contains benzyl alcohol. Benzyl alcohol ≥99 mg/kg/day can cause gasping syndrome and fatal toxicity in neonates. High concentrations and fast infusion rates may cause hypotension, hepatocellular necrosis, acute renal failure and circulatory collapse. Continuous infusions require PVC-free tubing (light-safe tubing is appropriate) and polyolefin or rigid PVC containers. Amiodarone contains 37% iodine by weight. It can cause hypothyroidism. Severe extravasation injuries can occur when administered through peripheral lines, particularly when administered rapidly (e.g . <1 hour)
Indication	Refractory supraventricular tachycardia (SVT) Post-operative junctional ectopic tachycardia (JET) Ventricular fibrillation (VF) or ventricular tachycardia (VT) Pulseless VF/VT during CPR
Action	Class III Antiarrhythmic agent. Amiodarone blocks sodium channels like class I drugs, exerts antisympathetic action like class II drugs and lengthens the cardiac action potential which is a class III effect. Amiodarone also blocks myocardial potassium channels, which contributes to slowing of conduction and prolongation of refractoriness. Its vasodilatory action can decrease cardiac workload and consequently myocardial oxygen consumption. It decreases sinus node and junctional automaticity, slows atrioventricular (AV) node and bypass tract conduction and prolongs refractory period of myocardial tissues (atria, ventricles, AV node and bypass tract).
Drug type	Antiarrhythmic agent.
Trade name	Cordarone X
Presentation	**IV** 150 mg/3 mL injection **ORAL** 100 mg and 200 mg tablet 5 mg/mL oral suspension (manufactured by pharmacy)
Dose	**To be prescribed and administered only upon the advice of paediatric cardiologist.** **SVT or JET** <u>IV</u> Loading dose: 6 mg/kg **over 4 hours** (equivalent to 25 microgram/kg/minute) then Maintenance: 5–15 microgram/kg/min[1-3] <u>Oral</u> 5-10 mg/kg/dose DAILY **Ventricular fibrillation (VF) or ventricular tachycardia (VT)** <u>IV</u> Loading dose: 5 mg/kg **over 1 hour**, then Maintenance: 5-25 microgram/kg/minute[3,4] **Pulseless Ventricular fibrillation or tachycardia (During CPR)** IV: 5 mg/kg as a rapid bolus.
Dose adjustment	Therapeutic hypothermia – No information. ECMO – No information. Renal impairment – No dose adjustment. Hepatic impairment - Use with caution due to reduced metabolism and/or hepatotoxicity
Maximum dose	IV/Oral: 15 mg/kg/DAY
Route	IV Oral
Preparation	IV: (Refer to special comments section for further essential information)

IV Infusion

Loading and maintenance dose - For infants <2 kg:

20mL Syringe

Draw up 0.4 mL (20 mg) of amiodarone and add 19.6 mL of glucose 5% to make a final volume of 20 mL with a final concentration of 1 mg/mL. Prepare loading and maintenance doses in 2 separate syringes.

50mL Syringe

Draw up 1 mL (50 mg) of amiodarone and add 49 mL of glucose 5% to make a final volume of 50 mL with a final concentration of 1 mg/mL. Prepare loading and maintenance doses in 2 separate syringes.

Prescriber to:

1. Order the dose (microgram/kg/minute) and
2. To calculate infusion rate (mL/hr) using the formula below:

Rate (mL/hr) = dose (microgram/kg/min) x patient's weight (kg) x 0.06

Maintenance dose (microgram/kg/min)		**5**	**10**	**15**	**20**	**25**
Rate (mL/hour)						
Weight (kg)	**0.5**	0.15	0.3	0.45	0.6	0.75
	1	0.3	0.6	0.9	1.2	1.5
	1.5	0.45	0.9	1.35	1.8	2.25

Loading and maintenance dose - For infants ≥2 kg:

20mL Syringe

Draw up 0.8 mL (40 mg) of amiodarone and add 19.2 mL of glucose 5% to make a final volume of 20 mL with a final concentration of 2 mg/mL. Prepare loading and maintenance doses in 2 separate syringes.

50mL Syringe

Draw up 2 mL (100 mg) of amiodarone and add 48 mL of glucose 5% to make a final volume of 50 mL with a final concentration of 2 mg/mL. Prepare loading and maintenance doses in 2 separate syringes.

Prescriber to:

1. Order the dose (microgram/kg/minute) and
2. To calculate infusion rate (mL/hr) using the formula below:

Rate (mL/hr) = dose (microgram/kg/min) x patient's weight (kg) x 0.03

Maintenance dose (microgram/kg/min)		**5**	**10**	**15**	**20**	**25**
Rate (mL/hour)						
Weight (kg)	**2**	0.3	0.6	0.9	1.2	1.5
	2.5	0.38	0.75	1.13	1.5	1.88
	3	0.45	0.9	1.35	1.8	2.25
	3.5	0.53	1.05	1.58	2.1	2.63
	4	0.6	1.2	1.8	2.4	3

IV bolus: Give undiluted

Oral: 5 mg/mL oral suspension (prepared by pharmacy).

Administration	**Administer through PVC free infusion set (e.g. light-safe infusion set) and polyolefin or rigid PVC containers. (Drug adsorbs onto PVC and leaches plasticiser from PVC).** **Do NOT use giving sets that contain diethylhexyl phthalate (DEHP).**

	Central line is recommended. **Peripheral line is used only if central venous access is not available: Severe extravasation injuries can occur when administered rapidly (e.g. <1 hour) or through peripheral lines.** **Central line: The minimum concentration should be 0.6 mg/mL and the maximum concentration should not exceed 6 mg/mL.** **Peripheral line: The minimum concentration should be 0.6 mg/mL and the maximum concentration should not exceed 2 mg/mL.** **IV loading dose:** Infuse over 4 hours for SVT/JET and over 1 hour for VF/VT. **Maintenance IV infusion:** Continuous infusion. **Oral:** May be given with or without feed.
Monitoring	**IV** Continuous cardiorespiratory monitoring Regular ECG recordings Close monitoring of blood pressure (rapid infusion may cause hypotension and circulatory collapse) Liver, thyroid and pulmonary function **ORAL** Monitor for liver, thyroid and pulmonary dysfunction.
Contraindications	Long Q-T interval syndrome[5] Second- or third-degree heart block (without pacemaker), Symptomatic bradycardia (without pacemaker) Sick sinus syndrome (without pacemaker). Allergy to amiodarone.
Precautions	Thyroid dysfunction, including goitre or nodules—increases risk of hypo- or hyperthyroidism. Lung disease (particularly with reduced diffusion capacity)—less reserve to cope with pulmonary adverse effects. Electrolyte disturbances (eg hypokalaemia, hyperkalaemia, hypomagnesaemia)—increase the risk of arrhythmias; correct before starting treatment if possible. Intravenous formulation contains Benzyl alcohol. This has been associated with gasping syndrome in neonates and infants.
Drug interactions	Cardiac arrest has been reported in neonates receiving amiodarone and dexmedetomidine.[6] Amiodarone forms a precipitate with heparin and may become ineffective.[7] Amiodarone potentiates oral anticoagulants. May potentiate the effects of highly protein bound drugs such as phenytoin. When introducing amiodarone maintenance dose of digoxin and flecainide should be reduced by half.[26-33]
Adverse reactions	Severe extravasation injuries can occur when administered through peripheral lines, particularly when administered rapidly (e.g . <1 hour). Hypotension, Cardiovascular collapse, hypothyroidism, hyperthyroidism, pulmonary alveolitis and fibrosis, hepatitis, grey skin discolouration, tremor, rashes, peripheral neuropathy, prolonged PTT, thrombophlebitis, corneal deposits.
Compatibility	Fluids: Glucose 5% ONLY. Y site: Alprostadil, amikacin, amphotericin B, atracurium besylate, atropine sulfate, bumetanide, calcium chloride, calcium gluconate, caspofungin, ceftaroline fosamil, ciprofloxacin, cisatracurium beshylate, clarithromycin, clindamycin, daptomycin, Dexmedetomidine, diltiazem, dopamine, doxycycline, adrenaline, erythromycin, esmolol, famotidine, fentanyl, fluconazole, gentamicin, insulin aspart, insulin regular,

	ketamine, labetalol, linezolid, lorazepam, midazolam, milrinone, morphine, naloxone, nitroglycerine, octreotide, pancuronium, phenylephrine, potassium chloride, tacrolimus, tirofiban, tobramycin, vancomycin, vasopressin, vecuronium and voriconazole.
Incompatibility	Fluids: sodium chloride 0.9% Y site: Ampicillin, azithromycin, bivalirudin, caffeine citrate, cefamandole, cefazolin, ceftazidime, digoxin, heparin, imipenem-cilastatin, , micafungin, pantoprazole, piperacillin-tazobactam, potassium phosphate, sodium bicarbonate, sodium phosphate, Sugammadex, tigecycline, and TPN CONFLICTING REPORTS Ceftizoxime, ceftriaxone, cefuroxime, dobutamine, furosemide, magnesium sulfate, sodium nitroprusside, noradrenaline.
Stability	Dilute immediately before use. For continuous infusion, diluted solution is stable for 24 hours at <25ºC in G5W in glass, polyolefin or rigid PVC containers including infusion time. Solutions containing <0.6mg/mL in Glucose 5% are unstable, Do not refrigerate.
Storage	Injection and tablets: ≤25°C (room temperature) 5 mg/mL oral suspension (manufactured by pharmacy): 2 to 8°C. Protect from light.
Excipients	Cordarone X IV solution - contains Benzyl alcohol, polysorbate 80.
Special comments	Adsorbs onto PVC and leaches plasticiser from PVC. Do NOT use giving sets that contain diethylhexyl phthalate (DEHP). For infusions lasting longer than 2 hours use rigid PVC or non-PVC bags and containers or bottles of glass and low adsorptive giving sets (BD Plastipak and Terumo syringes and light-safe tubing are PVC free and safe for use) Solutions containing <0.6mg/mL in Glucose 5% are unstable. Concentration >2mg/mL (maximum of 6 mg/mL) should be given via a central line, however peripheral IV use (maximum of 2 mg/mL) is permissible for shorter duration if no central venous access is available.[7]
Evidence	**Background** Amiodarone is a class III antiarrhythmic agent. It is used for both supraventricular and ventricular arrythmias in adults and children.[8] **Efficacy** **<u>Supraventricular tachycardia</u>** Atrioventricular reentrant tachycardia (AVRT) is the most common form of supraventricular tachycardia (SVT) in newborns. In some newborns, AVRT is recurrent and refractory to conventional antiarrhythmic therapy. The clinical effectiveness of amiodarone must be weighed against the likelihood of adverse effects. Adverse effects are less common in children than in adults. Etheridge et al assessed the safety and efficacy of amiodarone as primary therapy for supraventricular tachycardia in infancy. They evaluated the clinical course of 50 consecutive infants and neonates treated with amiodarone for supraventricular tachyarrhythmias. At presentation, congenital heart disease, congestive heart failure, or ventricular dysfunction were present in 24%, 36%, and 44% of the infants, respectively. Infants received a 7- to 10-day load of amiodarone at either 10 or 20 mg/kg/day. If this failed to control the arrhythmia, oral propranolol (2 mg/kg/day) was added. Patients were followed up for 16.0+/-13.0 months, and antiarrhythmic drugs were discontinued as tolerated. Rhythm control was achieved in all patients. Growth and development remained normal for age. Higher loading doses of amiodarone were associated with an increase in the corrected QT interval, but no proarrhythmia was seen. There were no side effects necessitating drug withdrawal.[2] Ciriello et al reported their experience with triple therapy (flecainide+propranolol+amiodarone) in a series of neonates who failed both first-line and second-line therapy for AV reentrant tachycardia.[1] Mean gestational age at the time of delivery was 36.7 ± 2.4 weeks. Mean weight at birth was 2.9 ± 0.6 kg. Mean age at the time of diagnosis of AVRT was 5.2 ± 7.4 day. Their typical workflow was to start flecainide as first-line therapy, with a starting dose of 3–4 mg/kg daily and titrated up to a maximum dose of 6 mg/kg daily. The alternative options were propranolol, sotalol or amiodarone alone. The starting dose of propranolol was 1–2 mg/kg daily and titrated up to 4–5 mg/kg daily; the starting dose of sotalol was 3–4 mg/kg daily and titrated up to a maximum dose of 6 mg/kg daily. They used amiodarone as first-line single

drug therapy only for newborns with severely impaired ventricular function, with an initial dose of 10 mg/kg daily and titrated up to 15 mg/kg daily. They proceeded to use triple therapy if first line or second-line therapy was inadequate. In the acute management of SVT refractory to other measures such as adenosine, they used intravenous amiodarone infusion (10 mg/kg/day). Mean duration of triple therapy was 226±73 days. The dosage of individual medications that maintained rhythm control were: flecainide 2.6±0.7 mg/kg daily + propranolol 1.4±0.5 mg/kg daily+ amiodarone 4.6±1 mg/kg daily. There was transient mild biochemical thyroid dysfunction that required dose reduction of amiodarone.[1] Similarly, Akin et al reported a case series of infants and children treated with a combination of amiodarone and propranolol for persistent SVT.[9]

Post-operative junctional ectopic tachycardia (JET)

Postoperative JET is a potentially life-threatening arrhythmia that is often resistant to conventional antiarrhythmic drugs. Kovacikova et al administered IV amiodarone in 40 paediatric patients with post-operative junctional ectopic tachycardia. Amiodarone 2 mg/kg IV bolus and, if necessary, as continuous infusion (10 to 15 microgram/kg/min), were used as the first-line therapy.[10] Amiodarone was effective in 45% of patients. In another study by Laird et al, IV amiodarone given in doses of 10 mg/kg, followed by an infusion of 10-15 mg/kg/day for 48-72 hours, appeared to be safe and effective for postoperative JET. They suggested long-term oral therapy is usually not necessary.[11]

Post-operative SVT and VT

Haas et al studied the haemodynamic response after IV amiodarone for supraventricular and ventricular tachycardias after corrective surgery for congenital heart defects. All patients received catecholamine infusions as standard post-op therapy to support cardiac function and output. In most cases a loading dose of 5 mg/kg of amiodarone was given over 1-4 hours followed by a continuous infusion at 10-20 mg/kg/day. After 1 hour, there was a significant improvement in heart rate and blood pressure. The catecholamine could be decreased as could the dose for sedation. They found that a slow IV bolus 5 mg/kg over at least 60 min followed by one or two additional boluses or a continuous infusion with 10-20 mg/kg day is a safe treatment strategy.[3]

Ventricular tachycardia/fibrillation

Burri et al evaluated the safety and efficacy of intravenous amiodarone as a single agent in infants (range 1-300 days) with life-threatening incessant tachycardias (17 supraventricular, 6 ventricular). At presentation, most infants were haemodynamically unstable. Amiodarone was given as an IV loading dose of 5 mg/kg over 1 h followed by an IV maintenance dose of 5 microgram/kg/min with stepwise increase up to 25 microgram/kg/min until arrhythmia control or side-effects occurred. Amiodarone was effective in most infants. The median time until arrhythmia control was 24 hours (range 1-96 hours) and the median maintenance dosage 15 microgram/kg/min (range 5-26 microgram/kg/min). Electrophysiological side-effects necessitating dose reduction comprised of sinus bradycardia and hypotension. Amiodarone administration was stopped in one patient with elevated liver enzymes.[4]

Pharmacokinetics

A pharmacokinetic study consisted of 266 plasma drug concentrations in 45 subjects with a median postnatal age of 40 days and weight of 3.9 kg. Mean IV bolus was 4.4 mg/kg and mean IV infusion was 10 microgram/kg/minute. The empiric Bayesian estimates for clearance (CL), volume of distribution at steady state, and terminal half-life were 0.25 (90% CL 0.14–0.36) L/kg/h, 93 (68–174) L/kg, and 266 (197–477) h, respectively.[12]

Safety

Hypothyroidism: Amiodarone contains 37% iodine by weight, and its structure resembles that of thyroxine(T4). Amiodarone therapy can induce hypothyroidism.[13-18]

Pulmonary toxicity and fibrosis: Acute pulmonary toxicity with IV amiodarone and pulmonary fibrosis with oral therapy have been reported.[19-21]

Prolonged QT interval: Fishberger et al reported 2 children who received amiodarone for ventricular tachycardia, although they were ultimately determined to have congenital long QT syndrome. Amiodarone is contraindicated in this setting and may have exacerbated the ventricular arrhythmia.[5]

Cardiovascular collapse: A multicenter study of 456 patients <= 18 years of age who received intravenous amiodarone identified cardiovascular collapse in 10% of patients. In multivariate analysis, age<3 months, baseline blood pressure <3rd percentile, and rapid bolus delivery ≤20 minutes were independent risk factors for cardiovascular collapse.[22]

	Other reported side effects with IV or oral route include elevated liver enzymes,[23] hyperglycaemia,[24] and phlebitis.[25]
Practice points	
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