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UK Surveillance of Surgical Ligation of the Patent Ductus Arteriosus in Premature Babies

- Abstract** This UK study aims to describe the incidence of surgical ligation of the patent ductus arteriosus (PDA) in premature babies born at less than 37 weeks gestation. We will describe: the general characteristics of these babies; the investigations which these babies undergo including echocardiography and the treatment of the PDA prior to the surgical ligation of the PDA. We will describe the respiratory and cardiovascular status of these babies at the time of PDA ligation and any post-ligation complications. We will describe the associated co-morbidities of chronic lung disease, necrotising enterocolitis, retinopathy of prematurity and intraventricular haemorrhage in this group of babies.
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- Background** The ductus arteriosus is a normal connection between the pulmonary artery and the aorta in the fetus which usually closes after birth. In premature babies the ductus arteriosus can remain open and is then called a patent ductus arteriosus (PDA). The abnormal flow of blood through the PDA causes haemodynamic effects including diastolic steal from the systemic circulation and increased pulmonary blood flow. It has been associated with chronic lung disease, necrotising enterocolitis, retinopathy of prematurity and intraventricular haemorrhage. It can also cause symptoms of cardiac failure and poor growth. Because of these haemodynamic effects and clinical associations, closure of the PDA may be clinically indicated. First line treatment is usually with medical treatment with non-steroidal anti-inflammatory drugs such as ibuprofen or indomethacin. If medical treatment is contraindicated or not successful, a small minority of premature babies are referred for surgical ligation of their PDA. Those who undergo surgical ligation are likely to be a sicker cohort of babies, with symptoms judged to be related their PDA, who have not responded to medical treatment or are too sick to have medical treatment. They are therefore an important group to study.
- Coverage** United Kingdom and the Republic of Ireland
- Duration** September 2012 – September 2013 (13 months of surveillance).
- Research Questions** Specific aims of the study are to:
1. Determine the incidence in the UK of premature babies who undergo surgical ligation of the PDA and to report the distribution by gestational age, birth weight, sex and ethnic group.
 2. Describe the clinical management and investigations including echocardiography prior to PDA ligation
 3. Describe the age, respiratory and cardiovascular support at the time of ligation
 4. Describe the post-ligation complications
 5. Describe the presence of chronic lung disease, necrotising enterocolitis, retinopathy of prematurity and intraventricular haemorrhage within those premature babies who undergo PDA ligation

Case Definition	Any baby born at less than 37 completed weeks of gestation, with no other structural cardiac abnormality, who, during the past month, has undergone surgical ligation of a patent ductus arteriosus before first discharge to home. Please note that a patent foramen ovale is not considered a structural cardiac abnormality.
Methods	<p><i>Surveillance</i> Active national surveillance of all premature babies who fulfil the case definition will be undertaken through the BPSU. As well as Consultant Paediatricians, Consultant Paediatric Cardiologists and Cardiothoracic Surgeons will be part of this surveillance. We aim to identify all babies born at less than 37 completed weeks of gestation, with no other congenital heart disease (PFO excluded) who undergo surgical ligation of a PDA prior to first discharge home.</p> <p><i>Questionnaires</i> We will send questionnaires to collect demographic and clinical data, including NHS/CHI number, Hospital Number, sex, date of birth, ethnicity, birth gestation, birth weight and clinical features prior to, at the time of and post surgical ligation of the PDA.</p>
Ethics approval	This study has been approved by NRES Committee - East Midlands – Derby (REC reference 12/EM/0149) and has been granted Section 251 NIGB permission under reference: ECC 3-02(FT6)/2012
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Collaborators	The British Congenital Cardiac Association (BCCA), Children's Heart (UK) Research Association CHUKRA
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