EFFECT OF PROSTAGLANDİN E1 TREATMENT ON PYLORİC WALL THİCKNESS İN NEWBORN PERİOD

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Study Protocol:

Effect of prostaglandin E1 treatment on pyloric wall thickness in newborn period

Intravenous prostaglandin E1 infusion is referred to as ductus dependent diseases, in systemic (aortic blood flow) circulation (eg critical aortic coarctation, intermittent arcus aorta, hypoplastic left heart, transposition of great artery), or lung blood flow through patent ductus arteriosus (For example, pulmonary valve atresia, tricuspid valve atresia, hypoplastic right heart) is a life-saving drug used to ensure that the duct remains open until a full, partial or temporary surgical correction or intervention is made. In the antenatal period, the placenta is a good source of prostaglandins. However, with the disappearance of the placental circulation after birth, many mechanisms ensure that the patent ductus arteriosus closes first functional and then anatomically. Due to these mechanisms occurring in the early days of life, babies who have ductus-dependent congenital heart diseases show themselves with severe clinical signs and symptoms such as cyanosis and circulatory disorders in this early neonatal period, when ductus begins to close when diagnosis and treatment are not performed. Echocardiography should be performed by the pediatric cardiology specialist as soon as possible after delivery to babies diagnosed in the antenatal period, and if a ductus-dependent congenital heart disease diagnosis is confirmed, PGE1 infusion should be started immediately, and the patient should be consulted with a pediatric cardiovascular surgery specialist and a surgical intervention plan should be provided as soon as possible.Due to these mechanisms occurring in the early days of life, babies who have ductus-dependent congenital heart diseases show themselves with severe clinical signs and symptoms such as cyanosis and circulatory disorders in this early neonatal period, when ductus begins to close when diagnosis and treatment are not performed. Echocardiography should be performed by the pediatric cardiology specialist as soon as possible after delivery to babies diagnosed in the antenatal period, and if a ductus-dependent congenital heart disease diagnosis is confirmed, PGE1 infusion should be started immediately, and the patient should be consulted with a pediatric cardiovascular surgery specialist and a surgical intervention plan should be provided as soon as possible. Prostaglandin E1 infusion is given as a continuous intravenous infusion. PGE1 has some side effects. The most common side effects are apnea, hyperthermia, and vasodilatation on the skin, they occur around 10-14% and are usually dose-related side effects. In addition, bradycardia, hypotension, convulsion, tachycardia, diarrhea, sepsis, necrotizing enterocolitis, hypernatremia, hyponatremia,

hypokalemia, respiratory depression, arrhythmia, congestive heart failure, gastric regurgitation, bleeding, anuria, hematuria and hypoglycaemia are more rare effects. The frequency and severity of these side effects usually depend on the dose of the drug and the time used. Many of these side effects disappear or decrease significantly when the medication is stopped or the dose is reduced. An important complication that can be seen with long-term use is cortical hyperostosis in long bones. Among the very rare side effects of the drug Prostaglandin E1 are hyperplasia of the gastric mucosa and the development of pyloric stenosis.Hypertrophic pyloric stenosis develops as a result of hypertrophy of circular pyloric muscles in the newborn period. Ultrasonography (USG) is the primary diagnosis and imaging method, because it does not contain radiation, it has replaced contrast studies. In ultrasonography, the thickness of the pyloric muscle from the mucosa to the serosa is more than 2-3 mm and the length of the pyloric canal is over 16 mm. In the literature, there is no study on the effect of PGE1 increasing the pyloric wall thickness in newborns, there is a case report from our hospital in this regard. In this study, we aimed to evaluate the effects of the drug on pyloric wall thickness prospectively with weekly ultrasonography measurements in infants given PGE1 infusion due to congenital heart disease. Ultrasonography measurements will be made at the bedside (with the ultrasonography device of our unit) by an experienced pediatric radiologist in pediatric cases. No intervention in the treatment, medical decisions and follow-up of patients will be made. Neonatal babies who were born in Hacettepe University Faculty of Medicine Ihsan Dogramaci Children's Hospital Neonatal Intensive Care Unit and who were receiving prostaglandin E1 infusion due to PDA-dependent congenital heart disease will be included in the study. Infants who do not have consent to participate, babies with chromosomal disease and hereditary metabolic disease will not be included in the study. In addition, babies who have an exitus in the first week of life and whose ultrasonography measurements cannot be obtained, and babies whose prostaglandin E1 infusion is discontinued by taking the second ultrasonographic measurement in the first week of life will be excluded from the study.

Study Design:

- Patients who have to receive Prostaglandin E1 treatment due to congenital heart disease followed in the neonatal department of our hospital will be included in the study after their consent and approval with their families without recording their identity information.

- Pyloric thicknesses will be measured by a pediatric radiologist once a week (at least twice) during the period when patients use PGE1.
- After reaching the sufficient number of cases (20 cases), increases in the pyloric wall thickness dimensions will be compared with statistical analysis. The number of cases was determined in accordance with the rate of hospitalization in our unit during the determined period (18 months). In this way, since the studies are in the form of a case report and the original article cannot be found in the literature, the observed power of the study will be calculated after the study is completed.