Title: EFFECT OF CHEST SHIELDING ON THE INCIDENCE OF PATENT DUCTUS ARTERIOSUS IN PREMATURE INFANTS UNDERGOING PHOTOTHERAPY

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Background:

The patent ductus arteriosus (PDA) is an extremely common problem in premature infants with a reported incidence of 70% in premature infants ≤ 29 weeks gestational age (GA) [1,2,3,4,5]. A persistent PDA has been associated with the development of neonatal morbidities such as pulmonary hemorrhage, bronchopulmonary dysplasia, intraventricular hemorrhage, necrotizing enterocolitis and retinopathy of prematurity [1,2,3,4,5,6,7,8].

Currently the treatment options for PDA closure consist of the use of nonsteroidal inflammatory drugs (NSAIDs) and/or surgical ligation. Despite its effectiveness, NSAIDs have serious side effects including renal dysfunction, decrease in blood flow to the brain, platelet dysfunction, intestinal perforation, and necrotizing enterocolitis [9,10]. Surgical PDA ligation may be associated with serious complications such as bleeding, vocal cord paralysis, chylothorax, ligation of arterial structures within the chest, pneumothorax and death [9,10]. In addition, a symptomatic PDA and its management often preclude provision of enteral nutrition and significantly delays time to reach full enteral nutrition affecting the overall health of the infant. Due to the serious complications of the current treatments, alternative methods to prevent PDA related symptoms are urgently required.

One such alternative method, may be to target the relationship between phototherapy and vasodilation of the PDA. The photorelaxation or dilation of blood vessels with light of a certain wavelength (420–460nm) has been verified in many animal studies and clinical studies in premature infants [11,12,13,14,15,16,17,18]. It has been speculated that phototherapy induced dilation of the PDA may be primarily seen in premature infants due to increased translucency of their premature skin [18]. Thus, it has been speculated that chest shielding during phototherapy may be a preventive approach to phototherapy induced dilation of the PDA in premature infants. Two small randomized clinical trials have evaluated the effect of chest shielding with aluminum foil during phototherapy on the incidence of PDA providing conflicting data [19,20]. These studies were performed in more mature infants, were open labelled, and involved use of
less intensive phototherapy. The LED phototherapy units in use since 2007 provide much higher irradiance in the range of 20 to 30 µw/cm²/nm. Therefore, the current LED units may be associated with a much more enhanced photorelaxation effect and higher incidence of PDA specifically in very premature infants.

Due to the possibility that current phototherapy units may be further enlarging the PDA, an effective preventative measure could consist of shielding the area of the PDA. Chest shielding would be a non-invasive preventive measure that could theoretically reduce the need for the use of NSAIDs and surgical ligation. The implementation of chest shielding could lead to early enteral nutrition, less need for parenteral nutrition, decreased complications from the PDA and its medical and surgical treatment, and decreased hospital stay and cost. The significance of our findings will be that it may provide evidence for a low cost non-invasive effective measure to prevent symptomatic PDA in premature infants ≤ 29 weeks GA or weighing ≤ 1000 grams at birth.

Hypothesis: Premature infants ≤ 29 weeks GA or ≤ 1000 grams at birth who have their chest shielded during phototherapy will have a lower incidence of symptomatic PDA

Aim: To evaluate if chest shielding with aluminum foil during phototherapy is associated with decreased incidence of symptomatic PDA in premature infants ≤ 29 weeks GA or ≤ 1000 grams at birth

Preliminary Data: In our recently published meta-analysis on chest shielding during phototherapy in preterm infants, Mannan et al. demonstrated that chest shielding during phototherapy may lead to a decrease in the incidence of PDA [21]. I’m currently performing a single center prospective double blind randomized pilot study on the effects of chest shielding on the incidence of PDA in preterm infants during phototherapy that has nearly completed enrollment. My next step is to perform a large multicenter trial looking at the effects of chest shielding on preterm infants. The pilot trial currently has funding via the Gerber Foundation Grant and I strongly feel there will be great interest from external funding sources for a large multicenter trial since chest shielding is a novel low cost noninvasive method to possibly prevent symptomatic PDA in premature infants. With the support of the Medical Device Innovations Program, I hope to collaborate with engineers and a medical device safety committee, from one of the nearby Universities, to produce a chest shield that is not only used for a large
multicenter trial but may also be incorporated into standard clinical care for all premature infants at risk for symptomatic PDA.

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