Dear Sir,

We welcome the comments of Alex Gillor regarding our evolving strategy for the management of the persistently patent arterial duct.\(^1,2\) It appears that his objections to our recommendation for closure of the “silent” duct are centred on several arguments, including

- the possibility that “informed consent” cannot exist in the absence of “complete” information regarding the natural history of the “silent” patent arterial duct;
- the uncertain long term risk of contracting endarteritis or endocarditis in the patient with a “silent” patent arterial duct;
- the significance of the morbidity and/or mortality to the patient who develops endarteritis, and
- the uncertain long term risks and outcomes of closure of the “silent” patent arterial duct.

Gillor believes that we cannot “provide appropriate information concerning the natural history of the “silent” duct; due to the fact that such information is not available.” We disagree. In our practice, informed consent is a “process of communication”\(^3\) that allows for the exchange of information between the family and the treating physician. It is typically not a singular event, but rather a dialogue that develops over time. The information that we provide our parents includes both the known natural history of the “audible” patent arterial duct, as well as the “unknown” history of the “silent” duct. We place particular emphasis on the fact that the true risk of endarteritis is unknown, and that we recognize that it is very low. Given the fact of anecdotal reports of endarteritis\(^4-9\) in association with the “silent” arterial duct, however, the risk cannot be zero. In an angiographic study of silent and audible patent arterial ducts, the authors found “no correlation between the presence of a murmur and the size of the arterial duct”.\(^10\) In another report of 14 children with infective endarteritis in association with patent arterial ducts, the authors noted “infective endarteritis mostly involved the small ducts”.\(^11\) In other words, size may not necessarily correlate with audibility or risk of infection. Although in the modern era of antibiotic therapy, the long term risk of infective endocarditis may be more “controllable”, we at The Congenital Heart Institute of Florida have had the experience of dealing with the catastrophic consequences of infective endocarditis. As noted by other authors, including a Japanese collaborative study on infective endocarditis, there is still significant morbidity and mortality, even in the best of circumstances.\(^12\)

Another point raised by Gillor is that “the authors can not provide adequate information concerning the outcome of interventional closed duct, as there are no long term studies available.” Again we disagree. Enough medium-term studies exist relative to interventional closure of the patent arterial duct.\(^13,14\) In addition, the use of stainless steel coils, such as Gianturco coils, in the systemic vasculature has an even longer history since its inception in 1975. In one study that specifically analyzed the results of protrusion of stainless steel coils into the aorta, no long term problems or complications were encountered.\(^15\)

The final point brought forward by Gillor quotes Hippocrates as stating “first, do no harm”. Gillor then uses this statement, allegedly from Hippocrates, as justification for the argument that “physicians that proclaim closure must provide an indisputable proof that closure is superior to nihilism”. Although in spirit, the Hippocratic Oath may reflect this philosophy, Hippocrates never stated “primum non nocere”. Had he made this statement, it certainly would not have been in Latin! The statement “first, do no harm” is a paraphrase of the statement, “As to diseases, make a habit of two things – to help, or at least to do no harm.” written by Hippocrates in Epidemics, Book I,
In a book by Inman from 1860, the specific expression of "primum non nocere", and its specific associated Latin, was traced back to an attribution to Thomas Sydenham, who was born in 1624, and died in 1689.\textsuperscript{18} We prefer the more modern version of the Hippocratic Oath that was proposed and implemented by the late Louis Lasagna, clinician, educator, and Dean Emeritus at Tufts University, which states in part, "I will apply, for the benefit of the sick, all measures [that] are required, avoiding those twin traps of overtreatment and therapeutic nihilism."\textsuperscript{19}

We believe that harm can be caused by both an act of omission and an act of commission. In other words, it can be harmful to initiate a dangerous and inappropriate treatment, and it can be harmful to withhold an appropriate and indicated therapy.

To summarize, we recognize that the treatment of the "silent" arterial duct is controversial, but we do not accept that the risk of endarteritis is zero. Furthermore, as the experience with percutaneous closure of the patent arterial duct increases, and the risk of intervention decreases, we are of the opinion that to obtain truly informed consent, intervention for all patent arterial ducts, including the "silent" ducts, needs to be part of the dialogue with the parents.

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References