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Editorial

Research in Nneonatology: The Need of Better Design Prospective Study

Over the years, most of the local studies that I reviewed in our paediatric fellowship exit examination were retrospective single centre studies. When we explored the reason behind such trend, the common answers were insufficient time to complete a project or lacking adequate samples. So, retrospective study often becomes a compromise of the reality. But when we encounter conflicting results, the final answer still must be derived from a well-designed prospective study. This issue illustrates some related limitations on establishing the genuine association or causative relationship by retrospective studies in several commonly encountered neonatal problems.

There are many studies focused on the adverse association between gestational diabetes mellitus (GDM) or maternal vaginitis with the outcome of pregnancy. The known sequalae are macrosomia and preterm birth. But using the comorbidity of both GDM and vaginitis as a combined risk factor is a relatively new angle. Interestingly, a study by Li Y, et al from Shanghai comparing the outcome of the newborn from 400 women with GDM and vaginitis and 705 women with GDM alone. It showed that women with GDM plus vaginitis tend to have a higher chance in getting a baby with macrosomia (20% vs 11.6%, $p<0.001$). This can be related to the underlying severity of the GDM. However, another finding seems to be conflicting to our common sense. That is GDM with vaginitis have a lower incidence of preterm and low birth weight baby than those with GDM alone. Since this is a retrospective study, it will be difficult to verify possible confounders such as increase surveillance of the GDM women with vaginitis. The authors also postulated that a different set of microbial flora with lower pro-inflammatory potential might exist. All these findings and postulations must be further examined by another prospective study.

The association of mechanical ventilation and hearing impairment is well known, and it was suggested that the noises generated by the ventilator might be the culprit. Whether non-invasive ventilation has similar impact on hearing is not as well defined. It is known that the bubble nasal continuous positive airway pressure (nCPAP) can induce significant noises. In the study by Deniz Y, et al, 442 neonates on NIV support were studied. It showed that NIV induced transient hearing abnormalities in early auditory screening. But such abnormalities do not translate into clinically significant hearing impairment as shown by subsequent confirmatory hearing assessment by auditory brainstem response and brainstem evoked response audiometry. When we reviewed the literature, there are different results and most of them are retrospective review with relatively small sample size. The impact of other cofounders such as used of ototoxic antibiotics also needs to be controlled by a well-designed study in the future. We now know that a specific mitochondrial DNA mutation (MT0RNP-1, m.1555A>G) is significantly related to aminoglycoside induced bilateral permanent hearing

loss. Therefore, pre-emptive pharmacogenetic screening for m.1555A>G has been proposed prior to the use of aminoglycosides.

Babies born from mothers who are drug addicts are at higher risk of having many adverse neonatal events. One of the well-known consequences is prematurity and baby may also suffer from drug withdrawal symptoms. In a local study by Wong WKW, et al, 103 babies born from drug addict mothers were studied. It was found 1/5 of them were premature and almost half of them suffered from neglect at birth. For some of them who declined follow-up, their children were also prone to have maltreatment, but such tendency could be minimised through active follow-up by the health-care providers and social workers such as the Comprehensive Child Development Service (CCDS). Some questions remain while we try to target the problems specifically. A prospective study with larger sample size in the future can further define various risk factors such as maternal age, types of drugs being abused, family background, etc. They can help us to identify proper intervention strategy and preventive measures.

Finally, a study by Meshram RM, et al illustrated how prospective randomised control trial could be conducted to answer simple clinical problems, even in the setting of low- and middle-income nations. Phototherapy for neonates with neonatal jaundice is a common therapeutic option in a neonatal unit for babies with significant unconjugated hyperbilirubinaemia. This Indian neonatal unit designed a randomised controlled trial to study the use of white curtain around a single-surface phototherapy unit and compared those with just a single-surface phototherapy alone. Due to the study design involving the use of white curtain or not, it must be an open-labelled study. Interestingly, it showed the total serum bilirubin level at all study time points were significantly lower in the group with white curtain. The mean duration of phototherapy was significantly shorter, and the rate of bilirubin decline was significantly higher also in the experimental group at all evaluated time points. The possibility that the white curtain may mask the baby from active monitoring is a major concern. However, it was shown that no adverse event occurred. Therefore, for limited resource neonatal unit, this is a reasonable alternative.

As shown by the Indian group, randomised prospective trial can be conducted even in limited resource setting. The key first step is to identify a clinical problem and look for measures to manage it properly. We highlighted these studies on neonates because among pediatric patients, neonatal unit have consistently higher patient volume, so it will be more feasible to conduct clinical study. The time factors and sample size issues can be overcome by collaboration, both locally and internationally. With a change in research culture, we expect more high-quality clinical research output can be generated from Asia.

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