#### Indian Academy of Pediatrics (IAP)





Newer Research and recommendations n Child Health



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# **UNDER THE AUSPICES OF THE IAP ACTION PLAN 2023**

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### Dear fellow IAPans,

### nRICH

Newer **R**esearch and recommendations In **C**hild **H**ealth-aims to bring you the abstracts of some of the breakthrough developments in pediatrics, carefully selected from reputed journals published worldwide.

Expert commentaries will evaluate the importance and relevance of the article and discuss its application in Indian settings. nRICH will cover all the different subspecialities of pediatrics from neonatology, gastroenterology, hematology, adolescent medicine, allergy and immunology, to urology, neurology, vaccinology etc. Each issue will begin with a concise abstract and will represent the main points and ideas found in the originals. It will then be followed by the thoughtful and erudite commentary of Indian experts from various subspecialties who will give an insight on way to read and analyze these articles.

I'm sure students, practitioners and all those interested in knowing about the latest research and recommendations in child health will be immensely benefitted by this endeavor which will be published online on every Monday.

Happy reading!

Upendra Kinjawadekar National President 2023 Indian Academy of Pediatrics



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Assessment of infant position and timing of stylet removal to improve lumbar puncture success in neonates (NeoCLEAR): an open-label,  $2 \times 2$  factorial, randomised, controlled trial.

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### **BASED ON ARTICLE**

Marshall ASJ, Scrivens A, Bell JL, et al. Lancet Child Adolesc Health. 2023 Feb;7(2):91-100.

### ABSTRACT

**Background:** Newborn infants are the highest-risk age group for bacterial meningitis. Lumbar punctures are therefore frequently performed in neonates, but success rates are low (50-60%). In Neonatal Champagne Lumbar punctures Every time-A Randomised Controlled Trial (NeoCLEAR), we sought to optimise infant lumbar puncture by evaluating two modifications to traditional technique: sitting position versus lying down and early stylet removal (stylet removal after transecting the subcutaneous tissue) versus late stylet removal.

**Methods:** NeoCLEAR was an open-label,  $2 \times 2$  factorial, randomised, controlled trial, conducted in 21 UK neonatal and maternity units. Infants requiring lumbar puncture at  $27^{+0}$  to  $44^{+0}$  weeks corrected gestational age and weighing 1000 g or more were randomly assigned (1:1:1:1) to (2/2 factorial groups) sitting position and early stylet removal, sitting position and late stylet removal, lying position and early stylet removal, sitting position and late stylet removal, lying position and early stylet removal, or lying position and late stylet removal using a 24/7, web-based, secure, central randomisation system. Block randomisation was stratified within site by corrected gestational age ( $27^{+0}$  to  $31^{+6}$  weeks,  $32^{+0}$  to  $36^{+6}$  weeks,  $37^{+0}$  to  $40^{+6}$  weeks, or  $41^{+0}$  to  $44^{+0}$  weeks), using variable block sizes of four and eight with equal frequency. Laboratory staff were masked to allocation. The primary outcome was successful first lumbar puncture, defined as obtaining a cerebrospinal fluid sample with a red blood cell count of less than 10000 cells per  $\mu$ L. The primary and secondary (including safety) outcomes were analysed by the groups to which infants were assigned regardless of deviation from the protocol or allocation received, but with exclusion of infants who were withdrawn before data collection or who did not undergo lumbar puncture (modified intention-to-treat analysis). This study is registered with ISRCTN, ISRCTN14040914.

**Findings:** Between Aug 3, 2018, and Aug 31, 2020, 1082 infants were randomly assigned to sitting (n=546) or lying (n=536), and early (n=549) or late (n=533) stylet removal. 1076 infants were followed-up until discharge and included in the modified intention-to-treat analysis. 961 (89%) infants were term, and 936 (87%) were younger than 3 days. Successful first lumbar puncture was more frequently observed in sitting than in lying position (346 [63.7%] of 543 vs 307 [57.6%] of 533;

adjusted risk ratio  $1 \cdot 10$  [95% CI  $1 \cdot 01$  to  $1 \cdot 21$ ], p= $0 \cdot 029$ ; number needed to treat=16). Timing of stylet removal had no discernible effect on the primary outcome (338 [ $62 \cdot 0\%$ ] of 545 infants in the early stylet removal group and 315 [ $59 \cdot 3\%$ ] of 531 in the late stylet removal group had a successful first lumbar puncture; adjusted risk ratio  $1 \cdot 04$  [95% CI  $0 \cdot 94 - 1 \cdot 15$ ], p= $0 \cdot 45$ ). Sitting was associated with fewer desaturations than was lying (median lowest oxygen saturations during first lumbar puncture 93% [IQR 89-96] vs 90% [85 - 94]; median difference  $3 \cdot 0\%$  [ $2 \cdot 1 - 3 \cdot 9$ ], p< $0 \cdot 0001$ ). One infant from the sitting plus late stylet removal group developed a scrotal haematoma 2 days after lumbar puncture, which was deemed to be possibly related to lumbar puncture.

**Interpretation:** NeoCLEAR is the largest trial investigating paediatric lumbar puncture so far. Success rates were improved when sitting rather than lying. Sitting lumbar puncture is safe, cost neutral, and well tolerated. We predominantly recruited term neonates younger than 3 days; other populations warrant further study. Neonatal lumbar puncture is commonly performed worldwide; these results therefore strongly support the widespread adoption of sitting technique for neonatal lumbar puncture.

### **COMMENTARY**

Lumbar puncture (LP) in newborn is a challenging procedure with variable success rates. Inability to perform LP leads to repeat procedure, risk of introducing infection, empiric prolonged treatment, prolonged hospital stays and parental distress. NeoCLEAR was a randomized controlled trial of 1082 infants [(term (89%), < 3days old (87%)] who needed a LP. They were assigned to either the sitting or lying position, and early or late stylet removal. The practitioners were trained with simulation and learning video. The primary outcome was successful first lumbar puncture, and the results showed that sitting position was associated with more successful first lumbar punctures than lying position (63.7% vs 57.6%), while early or late stylet removal had no effect (benefit or harm). Sitting was also associated with fewer desaturations and better heart rate stability during the procedure (93% vs 90%). However, there was one possibly related scrotal haematoma recorded in the sitting plus late stylet removal group. The benefits of better results with sitting position for LP have been attributed to increased interspinous distance, wider subarachnoid space and less infant struggling.

The study excluded infants on ventilator, those younger than 27 weeks gestation and beyond 44 weeks gestation

## PRACTICE POINTERS

- 1. For newborn infants requiring lumbar puncture, sitting position is superior, demonstrated to be safe, better tolerated and more successful in obtaining an interpretable cerebrospinal fluid sample, compared with lying position.
- 2. The study demonstrates sitting position is cost neutral, safe, well tolerated, and easy to learn. The study prompts a change in practice towards sitting technique as standard for neonatal lumbar puncture.
- 3. Clinicians currently are unfamiliar with sitting position for LP in newborn. This is an inexpensive ntervention that practitioners can learn with minimal training. The current practice of side lying down position for LP needs to be discouraged.
- 4. Further research is necessary to analyse the efficacy of different lumbar puncture techniques for preterm, older infants and children.

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