

- <http://rchiips.org/nfhs/pdf/NFHS4/India.pdf>. Accessed March 3, 2019.
- Dudeja S, Sikka P, Jain K, Suri V, Kumar P. Improving first-hour breastfeeding initiation rate after cesarean deliveries: A quality improvement study. *Indian Pediatr*. 2018;55:761-4.
 - Adhisivam B, Vishnu Bhat B, Poorna R, Thulasisingam M, Pournami F, Joy R. Postnatal counseling on exclusive breastfeeding using video - experience from a tertiary care teaching hospital, South India. *J Matern Fetal Neonatal Med*. 2017;30:834-8.
 - Laqshya – Labour Room Quality Improvement Initiative 2017. Available from: <http://nhsrcindia.org/sites/default/files/LaQshya-%20Labour%20Room%20Quality%20Improvement%20Initiative%20Guideline.pdf>. Accessed March 13, 2019.

Throwing the Baby out with the Bath Water: The Need for Reviewing Ethics Requirements

No one questions the need for ethics in medical publishing. The current norm for credible journals is on insisting on patient consent for all clinical data published, whether prospective or retrospective. Clinicians are constantly learning, whether from published studies or their own experience, and it is appropriate that we “practise” medicine all our lives, not having approaches set in stone. Published guidelines frequently change; they also exhort us to individualize care. Thus, clinicians observe patterns, or try something not quite well spelt in guidelines, and when it works well, repeat it in later patients. It is this experience, sometimes accumulated over decades, that gives us the ‘tricks of the trade.’

Many of us who maintain patient records find analyses of long-term data yield useful observations and evidence, which till very recently, were routinely published. But crucially, they cannot be predicted in advance. For example, with the same management approach, outcomes may differ because of demographic, economic or other factors. These intellectually satisfying exercises throw up hypotheses, which can be developed into formal studies. But having made an observation, how does one track down patients seen decades ago to take their consent? The easy answer: when you find something works well, plan a study, take approval from the Ethics Committee, obtain patients’ consent: since prospective data is better than retrospective. However, this theoretically sound approach ensures losing wisdom gleaned from experience, and burying potentially meaningful data. Imagine Fuller Albright or Harvey Cushing’s papers being rejected because patients’ consent forms were not available!

At this point, it is important to distinguish two

situations. Where routine management has been practised, if valuable patterns emerge, there should be no ethical dilemma in publishing aggregated data, which do not impinge on patients’ anonymity. Where clinician/s deviated from then-standard practices, thus affecting patients’ care, the need for consent is ethically imperative. Conflating these situations because of our recent increasingly obsessive concern about ethics discourages sharing learning, which is the very purpose of journals. Worrying, they could push clinicians reluctantly into the arms of predatory journals, which are an unfortunate reality.

Journals which have built up credibility the slow and hard way, must urgently find solutions. Credible journals must re-evaluate their policies, separating the groups where ethical clearance is redundant, and where it is indeed essential. Otherwise, all this worrying about consents and ethics clearances, would amount to throwing the baby out with the bath water.

ANJU VIRMANI

Pediatric Endocrinologist,

Max, Pentamed and Rainbow Hospitals, New Delhi, India.

virmani.anju@gmail.com

EXPERT’S REPLY

Ethical conduct of research is essential to safeguard research participants. All over the world, research is carried out only in accordance with the country’s National ethical guidelines. The author is referred to the 2017 Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical Research Involving Children [1]; wherein it is clearly stated that waiver of consent may be obtained in retrospective studies, where the participants are de-identified or cannot be contacted. Hence there will not be an issue in conducting retrospective studies.

SUVASINI SHARMA

Ethics Adviser, Indian Pediatrics

New Delhi, India.

sharma.suvasini@gmail.com

REFERENCE

1. Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research Involving

Human Participants. New Delhi: Indian Council of Medical Research; 2017. Available from: https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf. Accessed May 21, 2019.

Precocious Puberty in an Infant with Sotos Syndrome

Sotos syndrome is a rare genetic disorder characterized by statural overgrowth, distinctive appearance (downslanting palpebral fissures, long narrow face and chin, broad forehead, dolichocephalic large head), developmental delay, and intellectual disability [1]. The endocrine manifestations are rare.

A 3-month-old boy presented with enlargement of genitalia and rapid growth noticed since birth. There was no history of visual disturbances, seizures, head injury, or drug intake. He weighed 3.7 kg (Z-score +0.71) at birth and had delayed development. The weight, height and head circumference were 6.65 kg, 66.0 cm and 42.0 cm corresponding to +0.28, +2.12 and +0.41 Z-scores, respectively. The upper-to-lower body segment ratio was 2.5:1 (normal 1.7:1). He had broad prominent forehead, dolichocephaly, large ears and long chin. The stretched penile length was 4.9 cm (+2 Z-score), testicular volume was 10 cc, and there were no pubic hairs. A diagnosis of Sotos syndrome was considered in view of distinct facial features, overgrowth and developmental delay.

The routine hematological and biochemistry investigations were normal. Bone age was advanced (3 years). Serum prolactin, growth hormone, thyroid profile and tumour markers were normal. Baseline luteinizing hormone (LH) and follicle stimulating hormone (FSH) were 1.95 IU/L (normal 0.02-3.2 IU/L) and 1.59 mIU/mL (normal 0.10-1.5 IU/L), respectively. GnRH stimulated peak concentrations of these hormones were 17.02 IU/L and 5.01 IU/L, respectively confirming central precocious puberty. The pituitary MRI and cardiac echocardiography was normal. Clinical exome sequencing identified a pathogenic heterozygous stop gain mutation in the *NSDI* gene (c.2362C>T; p.Arg788Ter), confirmed by Sanger sequencing.

Child was started on 3-monthly injections of Leuprolide. Testicular volume regressed to 5 cc over next

8 months. At age of 4 years and 9 months, his weight, height, and head circumference were 19 kg (+0.97 Z-score), 112.6 cm (+1.77 Z-score) and 56 cm (+3.84 Z-score), respectively, and testicular volume was 4 cc.

Sotos syndrome shows clinical overlap with Weaver syndrome and other overgrowth syndromes during infancy, and the confirmation of diagnosis depends on the presence of *NSDI* mutations [1]. An increased upper-to-lower segment ratio is helpful in differentiating it from usual causes of infantile overgrowth [2]. The endocrine problems in Sotos syndrome include hypothyroidism, cryptorchidism, hypospadias, and hyperinsulinism [1,3]. Central precocious puberty has been reported very rarely [4,5]. Although bone age advancement due to accelerated growth velocity is common in Sotos syndrome, an unusual advancement as seen in our patient may indicate central precocious puberty [4].

SANIYA GUPTA AND DEVI DAYAL*

Department of Pediatrics,
Advanced Pediatrics Center,
PGIMER, Chandigarh, India.
*drdevidayal@gmail.com

REFERENCES

1. Tatton-Brown K, Cole TRP, Rahman N. Sotos Syndrome. *In: Pagon RA, Adam MP, Ardinger HH, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2019. 2004 Dec 17 [updated 2015 Nov 19].*
2. Dayal D, Soni V, Das G, Bhunwal S, Kaur H, Bhalla AK. Longitudinal observations on growth patterns of obese infants: Developing country perspectives. Preliminary study. *Pediatr Pol.* 2017;92:397-400.
3. Cerbone M, Clement E, McClatchey M, Dobbin J, Gilbert C, Keane M, et al. Sotos syndrome presenting with neonatal hyperinsulinaemic hypoglycaemia, extensive thrombosis, and multisystem involvement. *Horm Res Paediatr.* 2019 Mar 15:1-7. [Epub ahead of print].
4. Bertelloni S, Baroncelli GI, Tomasi O, Sorrentino MC, Costa S, Saggese G. [Sotos syndrome: follow-up of a case with precocious puberty]. *Pediatr Med Chir.* 1995;17:353-7.
5. Lim S. Central precocious puberty in a case of SOTOS syndrome (abstract). *In: 53rd Annual Meeting of the European Society for Paediatric Endocrinology (ESPE). Dublin, Ireland, September 18-20, 2014: Horm Res Paediatr.* 2014;82:1-507.