EDITORIAL

Galactosemia – A Not to be Missed Inborn Error of Metabolism

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The incidence of classical galactosemia in different countries has been reported to vary from 1 in 30,000 to 1 in 75,000 [1]. The exact population incidence in India is not known as there are no large studies available amongst low-risk population. In a recent study from Uttar Pradesh [2] about 13,500 newborns were screened, but no true positive case of galactosemia was detected. In another study from Andhra Pradesh [3], 10,300 babies were screened for Galactosemia; no case of galactose-1-phosphate uridyl transferase (GALT) deficiency was detected. This was probably due to small number of cases screened. If we extrapolate the reported incidence from the western world (1:30,000), about 87 babies every year are born with galactosemia in India. The prevalence of galactosemia in Indian children with suspected metabolic liver disease (MLD) has been reported to be about 20% [4], next to Wilson's disease and glycogen storage disorders. In our own unpublished data, high-risk (clinical suspicion, positive family history, *etc*) screening for galactosemia revealed prevalence of GALT deficiency as 12%.

The screening tests for galactosemia include a positive non-glucose sugar in urine (tested by Benedict's test or chromatography), with a negative glucostix test and measurement of Galactose-1-phosphate. Screening by urine reducing substances alone is not recommended as there is possibility of the test being false positive and false negative [5]. Erythrocyte GALT enzyme estimation is diagnostic of galactosemia. Galactosemia is classified as classical and clinical variant depending upon the level of GALT enzyme activity which is barely detectable in the former and about 1-10% in the latter. Although initial clinical features in either of them are similar, the long-term complications, including premature ovarian failure, are uncommon in clinical variant galactosemia. *GALT* gene mutation testing is advisable if available, and essential if prenatal diagnosis is to be planned. A definite genotype-phenotype correlation has been described and can be helpful in guiding prognosis [6]. A recent study from Northern India [7] highlighted the heterogeneity of mutations and importance of *GALT* gene analysis in the diagnosis of galactosemia in Indian patients. The same study also revealed that the mutational profile amongst Indians differs significantly from other populations.

There are varied views regarding inclusion of galactosemia in universal newborn screening programs as the outcomes have not been found to differ much in newborns diagnosed on newborn screening *versus* those detected early due to clinical suspicion and treated [8]. Even amongst siblings who were diagnosed and treated earlier, outcomes were similar [9].

Galactosemia is one of the rewarding inborn errors of metabolism (IEM) to treat. Special diets are easily available in India and are relatively much cheaper compared to diets for other metabolic liver diseases or IEMs amenable to special dietary therapy. In the present issue of *Indian Pediatrics,* Sen Sarma, *et al.* [10] from a pediatric gastroenterology setting of a tertiary care hospital have reported their retrospective experience of 24 (2% of all neonatal cholestasis cases) cases of galactosemia seen over 12 years. The clinical/laboratory profile, follow-up and predictors of outcomes have been discussed. The median (range) age of onset of symptoms and age at diagnosis /dietary intervention was 10 (3-75) days and 55 (15-455) days, respectively indicating delay in diagnosis. Of the 14 liver biopsies done 12 showed cirrhosis or bridging fibrosis. Out of 18 patients who were compliant with the diet, 87% cases survived. Follow-up for at least 6 months or more was available in 18 patients and all showed normalization of liver transaminases within a median time of about 6 months. Language delay in 6, fine motor problems and hyperactivity in one each was reported in 13 cases evaluated. Improvement in liver function was not influenced by high pediatric end-stage liver disease (PELD) scores but was significantly quicker in patients diagnosed before 4 weeks.

Available literature suggests that early diagnosis and treatment with lactose-free diet in initial 1-2 weeks of life reduces complications of liver failure and mortality.

However, most follow-up studies in patients with classical galactosemia suggest that despite adequate treatment from an early age, there is risk of cognitive, motor and speech problems. Additionally, almost all females with classic galactosemia manifest later in life with premature ovarian failure causing hypergonadotropic hypogonadism [11]. Developmental delay and speech problems have been described in about 50% of cases while motor function is reported to be impaired in about 18%. About 80% of girls have premature ovarian failure. Prediction of outcomes have been reported to be based on the level of erythrocyte GALT activity, genotype, compliance with therapy and age at which good therapeutic control was achieved.

The study by Sen Sarma, *et al.* [10] emphasizes need for early diagnosis and good response to dietary intervention even in severely affected cases. Small numbers, retrospective data and short-term follow up are the major limitations. None the less, there is a clear message for high index of suspicion, importance of early diagnosis and dietary compliance. This applies to many other easily and economically treatable IEMs.

Lactose-restricted diet is the presently recommended therapy for classical and clinical variant galactosemia. A very strict control is desired with no galactose in diet, more so in the initial stages. Any baby with clinically suspected galactosemia, should be initiated on soy-based diet till the time enzyme report is available. After the neonatal period, a strict lactose-free diet is controversial. Despite strict dietary control and early diagnosis, long-term complications are common as discussed above. The reason for long-term complications like neurodevelopmental impairment and hypogonadism is probably the endogenous synthesis of galactose or from abnormal galactosylation [12]. Newer therapeutic strategies targeted at controlling galactose 1-phosphate production should be worked on aggressively [11]. As inhibition of Galactokinase (GALK) is likely to prevent the accumulation of galactose-1-phosphate (which is probably the most toxic metabolite) from diet and endogenous sources, efforts towards making a therapeutic agent as small molecule GALK inhibitor seems promising. Some work in this direction has been initiated [13,14].

Meanwhile as we await better therapies, pediatricians should focus on early detection by keeping a high index of suspicion, early dietary intervention, ensuring dietary compliance, regular follow-up and early intervention for long-term complications.

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EDITORIAL

Classic Galactosemia: Indian Scenario

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Classic galactosemia is an autosomal recessive disorder of galactose metabolism due to deficiency of the enzyme galactose-1-phosphate uridyltransferase (GALT). Most affected babies develop severe manifestations such as failure to thrive, vomiting, diarrhea, hypoglycemia, hypotonia, jaundice (which is often unconjugated in the beginning) and cataracts within 1-2 weeks of starting milk feeding [1,2]. Without treatment, these babies progress to severe liver disease (hepatosplenomegaly, abnormal liver function tests, coagulopathy, cirrhosis, ascites), renal tubular damage and brain damage. Often they develop life threatening bacterial sepsis, most commonly due to *E. coli* infections. Fatality is high in untreated cases. However, response to withdrawal of galactose (milk) is almost dramatic in most cases – acute symptoms subside within a few days and liver functions improve rapidly to full recovery [1,3]. Nevertheless, long term outcome is somewhat frustrating, as despite early diagnosis and strict dietary therapy, many, inevitably demonstrate long-term complications such as cognitive and motor dysfunction, speech and learning difficulties (>70%), osteoporosis and hypogonadism with infertility (> 90% females) [4,5].

Galactosemia has a reported incidence of 1:30,000 to 1:60,000 in western countries [6]. Not much is known of the disease in India and published literature on the subject is scanty [7-9]. Galactosemia appears to account for upto 4% of neonatal cholestasis syndrome (NCS) in India [10]. In this issue of *Indian Pediatrics*, Sen Sarma, *et al*. [11] describe clinical features and outcome of a series of children diagnosed with galactosemia during the years 2003 to 2014 at the Pediatric Gastroenterology unit of SGPGI, Lucknow. All children in this series were essentially referred cases of NCS, and diagnosed as galactosemia through investigative protocols of NCS. The age at diagnosis in the series ranges from 15-455 days (mean of 55 days) and majority presented with advanced liver disease. It is obvious that severe cases, that present early to neonatal units, have not been included in this series. The Lucknow series is a retrospective analysis of 24 babies diagnosed as galactosemia, and who were well at discharge. The only two deaths alluded to were babies who were 'non-compliant' to therapy, and who were readmitted in the follow up period. This suggests a very optimistic outcome in treated cases, despite advanced liver disease and severe infections. Though patient data was collected over 11 years , the mean follow-up period of the survivors was only 30 months (range 6 – 78 months), and thus, inferences about long-term complications (as described in Western literature) [4,5], cannot really be made on the basis of this study.

The diagnostic tests for classic galactosemia are either detection of elevated erythrocyte galactose-1-phosphate concentration (difficult to estimate in India), or absent or barely detectable GALT enzyme activity (available now at many centers in the country). Assessment of urinary non-glucose reducing substances has been commonly used as a test for galactosemia, but this is only a screening test with significant number of false positive and negative results. Identification of bi-allelic mutations in the *GALT* gene, though still a research modality, can also be used as a diagnostic test for galactosemia. The GALT mutational profile in India appears to differ significantly from other populations studied, with N314D being the most common mutation with a frequency of 40% followed by Q188R at 2.7% [7]. Prenatal testing can be offered either by assessing GALT enzyme activity or molecular genetic testing (if disease-causing GALT mutations in the family are known). Molecular genetic testing is preferred over enzyme analysis.

Newborn screening for galactosemia has been a 'success' story in the west [6]. In the US, it is estimated that more than 80 babies with classic galactosemia are now identified at birth through the newborn screening programs, and for most of these infants, the potentially lethal sequelae of the disease are prevented by early intervention [6]. However, universal screening for galactosemia is not yet a 'reality' in our country, nor is it a priority [12], and as such, only increased awareness of the condition and a high index of suspicion can lead to early diagnosis and appropriate treatment.

The most important part of management of classic galactosemia is elimination of all galactose from the diet as soon as diagnosis is suspected [3,4]. This is one of the few conditions in which breast feeds must be stopped immediately, as also animal milk, and replaced by either calcium enriched soyamilk or lactose-free casein hydrolysates. Dietary treatment must be continued lifelong. In older children, complete elimination of galactose becomes difficult as many foods such as fruits, vegetables, breads and legumes contain significant amounts of galactose [3,4]. Moreover many recent studies have shown that such strict elimination may not even be desirable [2-4] though animal milk in any form must always be restricted. Infact, the major source of galactose even in well-controlled patients appears to be 'endogenous' production, and aim of future improved therapies would be to conceive of drugs to reduce endogenous production of galacose-1-phosphate, manipulate the metabolic pathways or stabilize the affected proteins [13].

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SPECIAL EDITORIAL

The Revised Guidelines of the Medical Council of India for Academic Promotions: Need for a Rethink

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Measuring academic achievements is never an easy task. This is particularly so when individuals are assessed for promotions in several fields with differing job descriptions. Assessment by peers is time-consuming and may be prone to bias; thus, objective criteria are required to minimize these concerns.

The Medical Council of India (MCI) has laid down guidelines for appointments and promotions of teachers in medical institutions in India. Among the criteria used for promotions, publication of research is an essential requirement. Though the need for this requirement has been debated, it is believed that the quality of teaching improves when medical teachers are involved in research. Many countries have made it mandatory for their medical faculty to do research; some other countries incentivize the conduct and publication of research. Reports have also lamented that the physician–scientist might become an endangered species [1,2]. Thus, linking publications with promotions might benefit both the individual and society. The flip side is that the time spent on research might take teachers away from teaching or clinical duties, particularly in under-staffed specialty departments. Further, the quality of research is likely to be poor when the resources and training in research are lacking [3]. Poor quality may even discredit research as a professional activity. Insistence on a certain amount of published research to maintain teaching credentials may lead to the phenomenon of 'publish or perish' [4]. Finally, it is important to consider that biomedical research may, at times, be relevant to non-biomedical journals and criteria for awarding credit to such publications should also be devised.

The MCI requires that the medical faculty engages in research. One measure to achieve this goal is the mandatory 'thesis' for postgraduate (Masters; MD/MS/DNB) and post-doctoral (DM/MCh/DNB) courses. Each student, regardless of specialty, is required to undertake a research study with a faculty member as the guide and often one-to-a-few faculty members from the same or related subjects as co-guides. Apart from providing training in doing research, the thesis is expected to inculcate an appreciation for research methodology and critical analysis. This experience is relevant to students who will become full-time researchers, and is also beneficial to medical practitioners who may never conduct further research but should be able to discern the merits of newer management options for their patients.

The MCI's initial guidelines for promotion to the position of Associate Professor and Professor required publication of at least two research papers by the candidates [5]. In September 2015, the MCI issued a

Note: This editorial is being published simultaneously in the *Indian Heart Journal, Indian Journal of Anaesthesia, Indian Journal of Gastroenterology, Indian Journal of Medical Ethics, Indian Journal of Medical Microbiology, Indian Journal of Occupational and Environmental Medicine, Indian Journal of Pathology and Microbiology, Indian Journal of Pharmacology, Indian Journal of Physiology and Pharmacology, Indian Journal of Urology, Indian Pediatrics, International Journal of Health Research & Medicolegal Practice, Journal of Anaesthesiology Clinical Pharmacology, Journal of Ayurveda and Integrative Medicine, Journal of Clinical and Scientific Research, Journal of Conservative Dentistry, Journal of Family Medicine and Primary Care, Journal of Indian Academy of Forensic Medicine, Journal of Mahatma Gandhi Institute of Medical Sciences, Journal of Postgraduate Medicine, National Journal of Integrated Research in Medicine, and The National Medical Journal of India*. It may also be published in forthcoming issues of other journals.

* See Annexure for endorsers. This editorial is not endorsed by all members of the IAMJE.

'clarification' on what constitutes 'research publications' for promotion of teaching faculty of medical colleges/ institutions in India (***Box* 1**) [6]. This 'clarification' raises the following issues:

Box 1 GUIDELINES FOR COUNTING RESEARCH PUBLICATIONS FOR PROMOTION OF TEACHING FACULTY OF MEDICAL COLLEGES/INSTITUTIONS IN INDIA AS LAID DOWN IN AN ORDER BY MEDICAL COUNCIL OF INDIA IN SEPTEMBER 2015

a. *Index agencies*: Scopus, PubMed, Medline, Embase/Excerpta Medica, Index Medicus and Index Copernicus

b. *Types of articles to be considered*: Original research articles and original research papers.

c. *Criteria for National/International journal*: Published by a National/International – specialty journal/journal of a national/ international society provided it is included in one of the indexes mentioned above.

d. *Authorship*: First author, second author

e. *E-journals*: E-journals not included

The above would also be applicable for 'accepted for publication' papers/articles.

E-JOURNALS

The new guidelines stipulate that publications in e-journals will not be considered for promotion. This guideline is probably in response to the proliferation of predatory journals, almost exclusively among e-journals, over the past five years. It is worrying that the largest number of authors and publishers seem to be from India [7]. Predatory publishing is perhaps a manifestation of the 'publish or perish' phenomenon with authors willing to pay for a publication [7].

While the MCI's corrective measure is laudable, the definition of 'e-journals' is variable [8]. We assume that the MCI implies e-journals are those that do not have a print version. This guideline would exclude many high-quality journals that are published only in the electronic format, e.g. the PLoS group of journals, the Biomed Central (BMC) journals, *British Journal of Clinical Pharmacology*, and *New Zealand Medical Journal*. It might also exclude journals that publish papers in a longer e-version and a shorter print version (*BMJ*). Many believe that 'paper journals' of niche specialties (with limited circulation) may soon cease to appear. Publishing is rapidly shifting to the electronic format and an explosive growth in e-journals is envisaged. Thus, the embargo on all e-journals seems unfair. The main objective of this guideline appears to be to limit predatory publishing and to ensure quality. This can be achieved by insisting on other criteria such as indexing, because reputed indexes are unlikely to include predatory journals.

INDEXING

Indexation or inclusion in select databases is an imperfect surrogate for quality. A more direct measure would probably be an assessment of each individual journal by peers. Till such an evaluation is available, we agree with the MCI's requirement that the journal of publication be listed in a recognized database. However, we suggest that the list of databases provided in the MCI's order needs a re-look. For example, Index Copernicus was last updated in 2014 [9]. Some journals listed on this index, and their publishers appear on Beall's list of potentially predatory journals [10]. In fact, Beall's blog says "Index Copernicus has no value" [11]. Although the MCI's order lists Medline and Index Medicus separately, these are actually one database. Similarly, PubMed is not a database but a search engine that searches various databases including Medline and PubMed Central. More important is the omission of Science Citation Index, an important database currently published by Thomson Reuters and of IndMed, a database of Indian medical journals, curated by the Indian Council of Medical Research. We suggest the following list of acceptable databases: Medline, PubMed Central, Science Citation Index, Embase/Excerpta Medica, Scopus and IndMed.

ARTICLE TYPES

The MCI guideline states that only 'Original research articles' and 'Original research papers' will be eligible for consideration. The objective here appears to be to include papers with original data and to exclude case-reports and reviews or opinions. However, this guideline is not precise because different journals classify original research variously under these two and some other sections, such as brief communications, short reports, etc. Further, this clause discredits meta-analyses and systematic reviews that involve scientific interpretation of original data. Instead of prescribing specific article-type labels, the MCI could suggest that the paper should report 'original research data or its interpretation in a meta-analysis or systematic review [12].' The guidelines' implication that case reports, reviews and opinion pieces should not carry any value remains debatable since these are an important part of scientific dialogue.

NATIONAL *VERSUS* INTERNATIONAL JOURNALS

The distinction between 'national' and 'international' journals is unclear. The inclusion of words such as 'India'

or 'Indian' in the title does not necessarily make a journal of lesser quality. Similarly, the presence of words such as 'international', 'global' or 'world' in a journal's name does not confer it with a higher quality. National journals are in fact more likely to publish research that is relevant to the local population. Again, this discrimination by the MCI appears to be a surrogate marker for quality. Since indexing has already been included as a criterion, the terms 'national' and 'international' have little value. We also suggest that the criterion of society journals be removed as indexation covers the quality requirements. The quality of a number of non-society journals (for example *The Lancet*) is widely recognized.

PLACE IN AUTHORSHIP SEQUENCE

Finally, the MCI guideline of limiting credit to only the first two authors of a paper is too restrictive. This guideline seems to be an attempt to weed out the malpractice of gift authorship. Again, the MCI's aim is laudable but the implementation can result in greater harm. The first name in a paper is generally associated with the person who did the maximum work and the last name being that of the supervising senior [13]. The MCI guideline suggests that other names except the first two on the byline are those of 'guests'.

The research scenario has moved towards collaborative and multidisciplinary projects conducted by large teams. To publish a paper in a high-quality journal, a researcher needs to look at a research problem from diverse aspects (*e.g.* clinical, laboratory, genetics, and immunology). Hence, good papers often have multiple authors with equal contribution, and all of them deserve equal credit.

The MCI guideline may not only deny credit to all those who have contributed, it may even encourage the practice of denying first authorship, and credit, to junior researchers whose contribution is often the maximum. Experience of many medical editors shows that it is not uncommon to find the senior-most author as the first author (even in case reports) due to the premium placed on this position [14]. Therefore, we suggest that this guideline should be removed, and all the authors of a paper should receive credit for it.

We appreciate the MCI's intention to give research its due recognition in academic institutions as well as for streamlining the process of promotion of teachers. Our suggestions to amend the existing guidelines, summarized in ***Box* 2**, can help remove ambiguities in the new MCI guidelines. These could also serve as the starting point of a wider consultation on the evaluation of research performance of medical teachers in India.

Box 2 OUR SUGGESTIONS

a) *Acceptable databases*:
Medline, PubMed Central, Science Citation Index, Embase/Excerpta Medica, Scopus and IndMed

b) *Types of articles to be considered*:
Articles reporting original research data or their interpretation in a meta-analysis or systematic review

c) *Authorship*:
All authors

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Annexure

The following members of the Indian Association of Medical Journal Editors (IAMJE) also endorse this editorial:

Zaffar Abbas, Editor, *JK Practitioner*
Philip Abraham, Former Editor-in-Chief, *Indian Journal of Gastroenterology*
Amita Aggarwal, Editor, *Indian Journal of Rheumatology*
S Bala Bhaskar, Editor-in-Chief, *Indian Journal of Anaesthesia*
Soumyadeep Bhaumik, Executive Editor, *Journal of Family Medicine and Primary Care*
KK Deepak, Executive Editor, *Indian Journal of Physiology and Pharmacology*
Chetna Desai, Chief Editor, *Indian Journal of Pharmacology*
Madhu C Divakar, Editor-in-Chief, *Hygeia: Journal for Drugs and Medicines*
Apul Goel, Associate Editor, *Indian Journal of Urology*
V Gopi Krishna, Editor-in-Chief, *Journal of Conservative Dentistry*
Anju Grewal, Chief Editor, *Journal of Anaesthesiology Clinical Pharmacology*
OP Gupta, Editor-in-Chief, *Journal of Mahatma Gandhi Institute of Medical Sciences*
Praveen Iyer, Assistant Editor, *Journal of Postgraduate Medicine*
Vishakha Jain, Assistant Editor, *Journal of Mahatma Gandhi Institute of Medical Sciences*
Amar Jesani, Editor, *Indian Journal of Medical Ethics*
SM Kadri, Editor-in-Chief, *Global Journal of Medicine and Public Health*
Arti Kapil, Editor, *Indian Journal of Medical Microbiology*
Vishwa Mohan Katoch, Editor, *Indian Journal of Leprosy*
GK Kulkarni, Editor, *Indian Journal of Occupational and Environmental Medicine*
Adarsh Kumar, Web Editor, *International Journal of Health Research & Medicolegal Practice*
Santosh Kumar, Associate Editor, *Indian Journal of Urology*
GM Malik, Chief Editor, *JK Practitioner*
Mohandas K Mallath, Member, Editorial Board, *ecancermedicalscience*
Vijay P Mathur, Former Member, Editorial Board, *Journal of Indian Society of Pedodontics and Preventive Dentistry*
Sundeep Mishra, Honorary Editor, *Indian Heart Journal*
Vatsala Misra, Editor-in-Chief, *Indian Journal of Pathology and Microbiology*
Alladi Mohan, Editor, *Journal of Clinical and Scientific Research*
Samiran Nundy, Editor, *Current Medicine Research and Practice*
Sanjay A Pai, Member, Working Editorial Group, *Indian Journal of Medical Ethics*
Bhushan Patwardhan, Editor-in-Chief, *Journal of Ayurveda and Integrative Medicine*
Amitabh Prakash, Editor-in-Chief, *Clinical Pharmacokinetics*
BS Ramakrishna, Editor-in-Chief, *Indian Journal of Gastroenterology*
V Raveenthiran, Editor, *Journal of Neonatal Surgery*
HPS Sachdev, Former Editor-in-Chief, *Indian Pediatrics*
Yogesh K Sarin, Editor-in-Chief, *Journal of Neonatal Surgery*
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