

(not mentioned in the article), without alteration or delay in the usual workup and management of biliary atresia. CMV positive biliary atresia patients have poorer outcome with reduced jaundice clearance, native liver survival and increased mortality [4]. We usually treat patients of BA associated with CMV with ganciclovir.

In our study, although 14% of patients presented with clinical ascites, most of them ($n= 11/14$, 78.6%) had normal or borderline albumin levels with normal bleeding parameters. Out of these, four patients had jaundice clearance, and were alive at 1 year. This cannot be considered as a poor outcome, especially considering the non-feasibility of primary liver transplantation in our country. Factors like scarcity of organs and centers offering pediatric liver transplant programs, financial constraints and need for lifelong immunosuppression, make Kasai's Portoenterostomy as the initial procedure of choice, even for patients with late presentations [1,5].

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Some Problems Associated with Generic Drugs

Ministries of Health and Family Welfare of Government of India and the states, and Medical Council of India (MCI) have mandated that doctors shall prescribe generic drugs only and no branded drug should be prescribed. It is presumed that reputed pharmaceutical companies maintain stringent quality control of their products as their reputation is at stake. The same may also be true of unbranded products, but the market is currently flooded with spurious or sub-standard drugs [1]. It should be presumed that the Government machinery must have put in some mechanism to ensure that no spurious or sub-standard drug is manufactured any where in the country, so as to provide high quality drugs at low cost. I would like to bring to notice of the concerned authorities some of the problems that doctors could face:

1. The issue of different doses of drug (e.g., dextromethorphan, paracetamol) in formulations from different companies has been raised in past [2-4].
2. Phenylephrine is not available as single salt for oral consumption, but is available in majority of cases in combination with Chlorpheniramine maleate, cetrizine or levocetizine. The combination of

phenylephrine with other molecules manufactured by different pharmaceutical companies have different quantities of different ingredients. Interchange of brands may result in up to 100% lower or higher dose of drug that may be ineffective in one case or very high dose resulting in toxicity in other case. Doctors usually know the composition of the brand of drugs they prescribe, and it may be difficult to write names and quantity of all the ingredients needed for a particular patient, and would not be possible for the pharmacist to identify the required products.

3. Dicyclomine is not recommended for children below six months of age. For infantile colic in children below six months of age, Simethicon, Dil oil and Fennel oil are often prescribed. Some manufacturers market products containing dicyclomine in addition to the other ingredients meant for use in children aged <6 months; clinicians may face difficulty in prescribing these drugs.
4. *Saccharomyces boulardii* is recommended for antibiotic-associated diarrhea, and recommended dose is 5 billion spores once or twice a day. There are few preparations of *S. boulardii* with 5 billion spores in each dose. If the doctors are not permitted to prescribe *S. boulardii* as a brand preparation, they will have to write probiotic *S. boulardii*, 5 billion spores once or twice a day. As on date, no generic preparation has 5 billion spores of *S. boulardii*. Pharmacist can hand over any probiotic or pre-

probiotic combination that has few million spores of *S. boulardii*, which may be 1/50th to 1/100th of the required quantity.

Such problems can occur with many other formulations, and are more likely to occur with formulations meant for children. The authorities should not only ensure the quality of drugs but also see that all similar drugs in the market are of uniform and rational formulations to avoid any mishap. These problems cannot be solved overnight. Till these issues are taken care of, the doctors should not be forced to prescribe only generic drugs.

Generic Drugs: A Call for Balanced Approach

Recently the Government of India and the Medical Council of India have called upon doctors to prescribe generic drugs or face action. We share our experience of prescribing by generic name- zinc sulphate syrup to a diarrhea patient, following which there was difficulty in procurement because either the pharmacist was unaware, drug unavailable, a substitute offered, branded drug choice given or informed not to buy for its doubtful potency and safety. The patient's parents appeared confused and at loss about how, where and whether to buy this 'new' medicine. This made us wonder whether prescribing generics really is a smart initiative.

Doctors appear hesitant or reluctant to use generics and they question their quality. Considerable amount of research in the area of equivalence of generic medicines has shown that generics can be used safely with no negative clinical impact [1-3]. These studies originate from countries with stringent regulations for generic drugs. However, to extrapolate these data to Indian scenario would not be appropriate as the regulatory environment prevailing in India is not robust raising questions whether the generics are as effective as branded drugs.

The drug regulatory system in the country suffers from inadequate manpower and infrastructure, ill-equipped drug-testing laboratories, lacks accurate drug information and database, has serious shortcomings in Centre-State coordination in the implementation of Drugs and Cosmetics Act and Rules, and is urgently in need of strengthening in terms of transparency and accountability [4]. Though actions have been initiated, they are far from

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satisfactory.

Asking doctors to prescribe generic drugs does not appear to be a rational prescription in the current healthcare system. Policy makers must take a holistic approach ensuring availability of quality generic drugs, raise awareness amongst patients, pharmacist and healthcare providers about advantages of these drugs, enforce stringent quality control measures at all levels of pharmaceutical chain, and roll out a time bound strategy in a phased manner. Ensuring drug safety and quality remains a top priority. Thoughtless implementation of policy is likely to lead to chaos, confusion, or worst a tragedy essentially preventable.

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