

Research in Neonatology: Need for Introspection

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This study was conducted to evaluate the quality of neonatal research published in major Indian journals. Four indexed Indian journals were scanned for topics pertaining to neonatology and the manuscripts were evaluated for the most important morbidity studied and its relevance to the national need. The analytical studies were evaluated for their quality of research methodology. Approximately 12% studies were pertaining to neonates and only one third of them were investigative in nature. Less than 20% studies were of national interest and only 5% of the total studies were community based. Although aims of the studies were clearly defined in 81%, sample size estimation was done in only 11%, blinding in 15% and one or more category of bias was seen in 84% of the studies. We conclude that there is an urgent need for interventional and community based studies in neonatology, on issues of national interest. A need was felt for improvement in the quality of research in neonatology with special emphasis on training in clinical epidemiology.

Key words: Neonatal research, Priority area, Quality of research.

Amongst all age groups, neonates are most susceptible to morbidity and mortality. This is evidenced by the fact that the major contribution of the infant mortality (67.6/1000) is by the neonatal mortality (43.4/1000) against the annual death rate of 9/1000(1). With improving health standards the infant mortality rate (IMR) has declined from 78.5/1000 live births in 1991 to 67.6/1000 live births in 2000, but there is no significant difference between the incidence of neonatal mortality of 1990 to that of 2000(1,2). Primary causes of neonatal mortality are sepsis, asphyxia, immaturity and malformations with sepsis topping the list in a community setting and low birth weight and immaturity precedes the other causes in a hospital setting(3,4). Only 25% of the deliveries in the country occur in hospitals, the rest three fourth take place at home(2), 88% of them are attended by untrained personnel, by traditional birth attendants, relatives or

friends. The reported coverage of antenatal care is 62%(2).

Some of the national issues of concern in neonatal research i.e. the problems of low birth weight, asphyxia and neonatal infections are to be probed further for greater understanding and to develop low cost technology for their prevention and management. Community studies are needed to validate and refine the sick newborn protocol, kangaroo mother care and mother baby package. Training in clinical epidemiology and perinatal biology need to be created to strengthen the foundation of neonatal research in the country.

Neonatology is a neglected entity by planner, administrator, community and the health personnel. The amount of research, the quality of research and the thrust area of research would bring to focus the needs and possible solutions for the continuing high neonatal morbidity and mortality. We planned

this study to evaluate the type of research in our country for the past 5 years in relation to its needs.

Methods

All articles related directly or indirectly to neonates, published in the four major journals *i.e.*, Indian Pediatrics, Indian Journal of Pediatrics, Indian Journal of Medical Research and the Journal of Obstetrics and Gynecology of India were reviewed. The articles included only those published between January 1996 to June 2001. A complete evaluation of the articles was made and the details recorded as per specially designed proforma. The information included the most important neonatal morbidity relevant to the national or local needs, whether the study was community or hospital based and whether the study was from a private sector or a government institution.

The quality of analytical studies was assessed by recording the study design, details of patients assignment into the study, assessment of outcome measures, analysis of data and the bias involved.

The study was considered to be of national interest when the area under research was the epidemiology, diagnosis, management, course and prevention of the most common neonatal morbidities. The most common neonatal morbidities considered of national interest were low birth weight, asphyxia neonatorum, neonatal sepsis, and neonatal jaundice.

Research reports related to the improvement of perinatal outcome, breast-feeding and long-term developmental assessment of low birth weight babies were also considered to be of national interest. The studies in which the subject of interest was the demography, the regional needs or when the results of the study were applicable only to the local population, it was considered to be a report of local needs.

Results

Out of 3000 publications, 355 (11.8%) studies pertained to neonates over a period of five and half years. There were 113(31.8%) analytical studies and 242(68.2%) studies were of descriptive nature. Nineteen percent of the published articles were on subjects of national need whereas 20% of those were on subjects of local or regional needs. 94.4% of the studies were hospital based and only 5.6% of the studies were community based. 81% of the studies were from government institutions or hospitals; only 17% were from the private hospitals (*Table I*).

Amongst the 113 analytical studies, there were 31(8.7%) experimental studies, 43(12%) cohort studies, 28(7.9%) case control studies and 11(3.1%) correlational studies. Only one third of the studies were related to the national needs. 3.5% of analytical studies were community based and only 11 % of the studies were from private institutions (*Table II*).

Studies on infections(5), low birth weight(5), perinatal outcome(3), breast-

TABLE I—Type of Studies Included in the Present Analysis

Study Design	Number	National Need	Community Based	Government Institutes
Analytical Studies	113	38	4	100
Descriptive Studies	242	22	16	187
Total	355	60	20	287

feeding(2) and jaundice(1) contributed to 52% of the interventional studies(16). Among these some were related to the local need only. There was no experimental study on perinatal asphyxia. Among the other analytical studies (cohort, case control and correlational) 19(23%) were on low birth weight, 13 (15.8%) on perinatal outcome, 8 each on infection and asphyxia (9.7% each), 6 (7.3%) on jaundice and 5 each on breast-feeding and growth and development(6%). There were only two long-term studies on development of high risk neonates.

Majority of the descriptive studies were on subjects of no national importance. 15 (6.2%) studies were on low birth weight and immaturity, 28 (11.6%) on neonatal infections, 14 (5.8%) on breast-feeding, 11 (4.5%) on jaundice and 10 (4.2%) on growth and development (*Table III*).

Quality of the analytical studies

In 81 % studies (92/113) aims of the study were clearly stated where as sample size estimation was done in only 11% of the published articles. Similarly blinding of the investigators was done in only 11 of the 71 studies (15%). Patient assignment details

analysis revealed that in 78% of the studies eligibility criteria were stated and there was no discrepancy between the inclusion and exclusion criteria. Either randomization or matching of patient as required for the respective studies was done in 43% (27/62).

Outcome measures were clearly stated in 58 of the 74 studies where it was required and appropriate statistics were applied in 74% of the studies but external validity of the study was proven in only 6 studies (6%). One or more category of bias was seen in 84% of the studies (*Table IV*).

Discussion

The four common indexed Indian journals were chosen to know the researches undertaken on various neonatal problems. The hierarchy of research involves the progression of work from case reports to case series, case control studies, cohort studies and finally to experimental studies. Randomized controlled trials are the answers for many of the research issues of importance (5). Nearly two thirds of the reported studies were of descriptive nature implying the lag in research in our country. Among the analytical studies only 8.7% studies were experimental. This indicates the

TABLE II—Type of Studies Published in Last 5 years in 4 Indexed Journals

Study Design	Number	National Need	Community Based	Government Institutes
Experimental	31 (8.7)	08 (2.3)	1	23 (6.5)
Cohort	43 (12.1)	16 (4.5)	2	41 (11.6)
Case control	28 (7.9)	10 (2.9)	1	26 (7.3)
Correlational	11 (3.1)	04 (1.3)	0	10 (2.9)
Surveys	33 (9.3)	10 (2.9)	8 (2.3)	22 (6.2)
Case series/reports	116 (32.6)	00	0	85 (23.9)
Reviews	25 (7)	10 (2.9)	0	25 (7)
Other descriptive studies	68 (19.2)	10 (2.9)	8 (2.3)	55 (15.5)
Total	355 (100)	60 (19)	20 (5.4)	287 (81)

TABLE III—*Areas of Research Covered in Neonatal Studies*

	Experimental		Other Analytical		Descriptive studies	
Low birth weight	5	(16)	19	(23)	15	(6.2)
Infections	5	(16)	8	(9.7)	28	(11.6)
Asphyxia	0	0	8	(9.7)	3	(1.2)
Jaundice	1	(3.2)	6	(7.3)	11	(4.5)
Breastfeeding	2	(6.4)	5	(6)	14	(5.8)
Growth and development	0	0	5	(6)	10	(4.2)
Resuscitation	1	(3.2)	1	(1.2)	6	(2.5)
Perinatal outcome	3	(9.6)	13	(15.8)	17	(7)
Others	14	(45)	17	(20.7)	138	(57)
Total	31		82		242	

Figures in parenthesis indicate percentages.

TABLE IV—*Evaluation of Study Quality in Neonatology*

Study design	Number	Aims stated	Sample size estimated	Matching/ Randomization done	Blinding done	Bias present
Experimental	31	26	5	12	4	26
Cohort studies	43	36	7	9	4	36
Case control	28	21	1	6	2	23
Correlational	11	9	0	0	1	10
Total	113	92 (81.4)	13 (11.5)	27 (43)	11 (15)	95 (84.1)

Figures in parenthesis indicate percentages.

long distance we need to cover to reach the research summit.

Though 75% of the deliveries occur at home under the auspices of trained and untrained dais, only 5.6% studies and 3.5% of the analytical studies in particular, were community based. This is possibly because of lack of motivation and inherent difficulties in conducting quality community studies. The other reason could be the poor networking and linkage of our primary health centers to the referral institutes. Referral and back referral of

patients between the primary care centers and the referral institute is hardly ever practiced.

Majority of these studies were from the medical colleges and a select few regional institutes such as All India Institute of Medical Sciences (AIIMS), Post Graduate Institute of Medical Education and Research (PGIMER) and Jawaharlal Institute of Post graduate Medical Education and Research (JIPMER). Private institutions hardly contribute to the research issues though they cater to the most of the urban and semi urban community. Kasturba

Key Messages

- Research in neonatology is far behind the expected needs of the country
- There is an urgent need for interventional and community based studies on issues of national interest.
- Training on clinical epidemiology is a must to improve the quality of research in neonatology.

Medical college (Manipal) and Christian Medical College (Vellore) are the only two private institutes that figure prominently in the context of neonatal research.

It is encouraging that 39% of the studies were on subjects of either national or regional need. Moreover nearly 52% of the interventional trials were on issues of national interest. However there was not even a single interventional trial on prevention of low birth weight or perinatal asphyxia. The deficit of long-term studies is quite obvious. A similar report published in 80's observed the lack of studies on perinatal asphyxia and also the deficit of follow up studies(6). The quality of the studies was analyzed based on the published manuscript. Though in majority of the manuscripts eligibility criteria were well stated, the study designs were flawed in 57% of the studies either randomization and matching were absent or inappropriate or in only 15% blinding was done when it were required. One or other bias was noted in 84% of the analytical studies though appropriate statistics were applied in 74% of the studies. These deficits reflect the need to create training in clinical epidemiology and perinatal biology among the Indian physicians and of course among the young graduate and undergraduate medical students.

Research published in Indian journals of repute was studied and hence the study is not a total reflection on the complete research done

in India. Our intention was to evaluate the results of research that is easily accessible to the Indian physician.

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