RESEARCH PAPER

Services for the Detection and Treatment of Retinopathy of Prematurity in Major Indian Cities: The 11-City 9-State Study

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Objective: Control of visual loss from retinopathy of prematurity requires high quality neonatal care, and timely screening and treatment of sight-threatening disease. We assessed services for retinopathy of prematurity provided by ophthalmic training institutions in major Indian cities.

Methods: Eleven cities were purposefully selected and eye-care facilities were evaluated using predefined criteria. Field teams visited these facilities to collect data by interview and observation using structured questionnaires.

Results: 30 training institutions were visited (18 public; 12 not-for-profit); 24 (24/30, 80%) provided a service for retinopathy of prematurity in 58 neonatal units (30 public, 28 private). 15/24 (63%) screened in one unit; six (25%) in 2-3 units and three (12%) in >3 units. Not-for-profit facilities (*n*=9) screened in more units than public facilities (*n*=15)(mean (range) 4.5 [1-12] vs 1.1 [1-2] units). Indirect ophthalmoscopy by ophthalmologists was the commonest screening modality but only half of these visited the units weekly. Laser was the commonest treatment, but only half treated babies in the neonatal unit. Annual treatments ranged from 1-200 (mean 39).

Conclusion: Eye-care services for retinopathy of prematurity need to expand, particularly in the government sector.

Keywords: *Challenges, Eye-care services, Screening, Situational analysis.*

The control of visual loss from retinopathy of prematurity (ROP) requires high-quality neonatal care with regular screening of infants at risk of sight threatening ROP, followed by urgent treatment where the risk of progression to retinal detachment is high [1]. These activities need scaling-up in India to be commensurate with the recent increase in services for sick newborn and preterm infants in public and private sectors [2,3]. The National Neonatology Forum of India (NNFI) has outlined guidelines for screening and treatment of ROP [4], but as control of ROP is not yet a specific policy of the Ministry of Health, the availability of services for ROP is not known.

In 2014, the United Kingdom's Queen Elizabeth Diamond Jubilee Trust agreed to support model programs to reduce the incidence of diabetic retinopathy and ROP in India, and for the detection and treatment of both conditions. The initiative focuses on scaling up control in Government facilities for diabetics and for preterm infants, and to build the capacities of eye care providers in the public sector. In order to inform strategies, an initial situation analysis of services was undertaken in the largest cities in India. Findings in relation to diabetic retinopathy have been published [5], and the purpose of this paper is to report the findings in relation to ROP in a subset of the facilities visited, focussing on training institutions who are likely to provide services in units in the public sector.

Methods

The situational analysis for diabetic retinopathy focused on the largest cities in India, and in each city eye-care providers from different health sectors were selected for inclusion in the study. During visits to eye-care providers, information on the services they provide for ROP was also collected.

For the purpose of this study, the following operational definitions were used:

Public funded facilities: financed and controlled by national or state governments or statutory bodies.

Private-funded facilities: financed by organizations or individuals on their own, including not-for-profit (NGO-run) facilities as well as for-profit agencies/individuals.

More populated/larger metropolitan cities: Those with a population ≥7 million, and less populated/smaller metropolitan cities as those with a population <7 million.

Standalone facilities: Facilities which provide only eye care, irrespective of the size of the facility. This could

include single practitioner clinics or hospitals with a large team of eye-care professionals.

Multispecialty: Facilities with many specialty medical services including eye care, including polyclinics and large hospitals with both out-patient and in-patient facilities.

Teaching: Facilities with postgraduate residency programmes recognized by the Medical Council of India (MCI) and the National Board of Examinations (NBE), (*i.e.* Diplomate of National Board (DNB), MD and MS) or post-doctoral specialty fellowships. In India, the DNB residency, which lasts three years, is in general ophthalmology and may not include sufficient exposure to medical or surgical retina, unlike MD/MS residency programmes which usually do include these specialities.

Non-teaching facilities: Facilities without formal training programmes approved by MCI or NBE for medical graduates.

Study location

A wide consultative process was adopted to decide where the study would take place and the cities to be included. As the prevalence of diabetes is higher in urban than rural areas, a decision was made to focus on services in urban areas, recognizing that these would probably represent the best available in India. Many services in urban areas are tertiary-level referral centres for neighbouring districts and smaller towns in the vicinity. If services in these cities were sub-optimal, it is highly unlikely that services in smaller cities and towns would be better. Information on services for ROP, which focussed on screening and treatment of acute, sight-threatening ROP (*i.e.*, Type 1 ROP, according to the Early Treatment of ROP trial, ET-ROP), was collected from all eye-care facilities included in the study.

All cities in India were ranked by population size (2011 census) [6] and the 10 most populous cities were selected. As only one city (Kolkata) was in eastern India, the twin-cities of Bhubaneswar and Cuttack were included to broaden geographical representation. Eleven cities were finally included in the study (***Table* I**).

Two-stage systematic stratified random sampling was used to select facilities for inclusion. Cities were initially stratified based on their population (more than or less than 7 million) with a higher number of health facilities being included in bigger cities. A list of all government hospitals with an eye department and private practitioners was then drawn up for each city through internet searchers and through professional contacts. Facilities were then selected for inclusion.

The size of the health facility and sector (i.e. public funded; private-for-profit; private-not-for-profit) were used to identify facilities for inclusion. Eye care facilities were classified as (*a*) large dedicated eye hospitals (20 or more beds with sub-speciality services), (*b*) eye hospitals with satellites facilities (i.e. facilities in more than one location under joint management), (*c*) eye departments in general multidisciplinary hospitals, and (*d*) eye practitioners (individual ophthalmologist practice).

In large cities, 4-5 large government eye care facilities and 4-5 large private eye care facilities were

TABLE I CITIES INCLUDED IN THE STUDY AND RELATED INFORMATION

City, State	*Population (2011)*	*Number of eye care facilities*	
		Included in DR study	*Included in this study*
Mumbai, Maharashtra	18,414,288	8	3
Delhi, Delhi	16,314,838	14	8
Kolkata, West Bengal	14,112,536	6	4
Chennai, Tamilnadu	8,696,010	7	3
Bengaluru, Karnataka	8,499,399	9	3
Hyderabad, Andhra Pradesh	7,749,334	7	3
Ahmedabad, Gujarat	6,352,254	9	2
Pune, Maharashtra	5,049,968	6	2
Surat, Gujarat	4,585,367	8	1
Jaipur, Rajasthan	3,073,350	9	1
Bhubaneshwar & Cuttack, Orissa	1,540,974	3	0
Total		86	30

DR = diabetic retinopathy.

randomly selected if there were more than this number. In smaller cities, 2-3 were selected, in large and small cities, 1 or 2 not-for-profit eye-care facilities were randomly selected if there were more than this number. In large and small cities, 4-6 private-for-profit eye practitioners were purposively selected, or snow-balling was used to identify additional facilities until the desired number had been reached.

Methodological approach

Mixed-methods *i.e.* qualitative and quantitative techniques were used to collect data from eye-care facilities. The data collected sought to assess whether certain of the NNFI guidelines were being implemented *i.e.*, that inpatient screening should take place in the NICU under the guidance of a neonatologist, and treatment should be carried out in the unit or in a setting where monitoring, resuscitation facilities and trained personnel are available.

Data collection instruments: A consultation of key stakeholders was organized to finalize the scope of the study, the methods to be used and data-collection instruments. A structured questionnaire was administered to the Senior Administrator and the Head of the Ophthalmology Department, in-depth interviews were conducted with Department / Institution Heads and an observation checklist was used to assess available equipment and services. The data-collection instruments were pre-tested in an eye hospital and a general hospital in Medak District, Telangana. Some questions were subsequently dropped or modified. The final data-collection instruments were translated into eight Indian languages: Hindi, Telugu, Tamil, Oriya, Bengali, Gujarati, Marathi and Kannada.

Assessment of infrastructure in eye care: The six elements of the World Health Organization's framework for health systems were used as the basis for data collection: i.e. number of staff and their skills; availability of infrastructure, equipment, laboratories and medication; whether clinical guidelines and protocols were available as well as information for patients. All interviews were audio-recorded after obtaining permission from respondents. All interviews are transcribed and translated into English for analysis.

Data collection teams: Five dedicated teams each comprising a public health specialist/senior researcher from Indian Institute of Public Health (IIPH), a trained interviewer and two research assistants collected the data after a three day period of training at the IIPH, Hyderabad. Training included mock interviews and pilot studies in two locations, in Medak district, Telangana State.

Data management and analysis: Databases for all questionnaires and observation checklists were created in MS Access 2010 which included validation, skip patterns, drop down menus and formulas to reduce data entry errors. Data were entered by trained data entry operators. Databases and codes were password protected and stored in three different locations. Data were transferred into Stata and R-software for analysis after cleaning. Numerous cross tabulations were performed, focusing on the counts/frequencies by type of facility.

Ethical approval was obtained from the Institutional Review Committees of London School of Hygiene, and Tropical Medicine and the Indian Institute of Public Health, Hyderabad. Written informed consent was obtained from institutional heads.

RESULTS

A total of 86 eye-care providers were included in the study of services for diabetic retinopathy (***Table* I**). For the ROP analysis, 56 facilities were excluded as they were small private-for-profit clinics or eye hospitals / eye departments not registered as training institutions, leaving 30 for analysis; 18 were training institutions in the public sector and 12 were in the not-for-profit sector. Twenty four (24/30, 80%) of these eye care institutions provided a service for ROP. The proportion of multispecialty general hospitals with an eye department (n=16) with a service for ROP was similar to that of specialist tertiary eye-care hospitals (n=14) (43% *vs.* 37%, respectively). The difference was more pronounced among public facilities (n=18) than not-for-profit facilities (n=12) (50% *vs*. 30%, respectively). Facilities in large cities (n=24) were also more likely to have a service for ROP than those in smaller cities (n=6) (63% vs 17%, respectively).

NICUs/SNCUs included in the ROP service: The number of government and private NICU/SNCU receiving a service for ROP from public and not-for-profit sector eye-care facilties are shown in ***Table* II**. A total of 58 NICU/SNCU were receiving a service for ROP, 30 NICUs were in the government sector and 28 in the private sector. None of the public funded eye care facilities worked in private NICU whereas not-for-profit eye care facilities worked in public and private NICU/SNCU.

Fifteen of the 24 eye-care facilities providing a service for ROP (15/24; 63%) screened in just one NICU/SCNU; 6 (25%) screened in 2-3 units and 3 (12%) screened in more than 3 units. Not-for-profit facilities (n=9), most being tertiary-level eye hospitals, provided ROP services in a larger number of units than public funded facilities

TABLE II NEONATAL INTENSIVE CARE UNITS AND SPECIAL NEONATAL CARE UNITS RECEIVING SERVICES FOR RETINOPATHY OF PREMATURITY FROM PUBLIC AND NOT-FOR-PROFIT PRIVATE SECTOR EYE- CARE TEACHING INSTITUTIONS (*N*=30)

	Government NICU/SNCUs			*Private NICU/SNCUs*			
Number of NICU/SNCUs receiving ROP services per eye facility	*From public eye facilities No. (%)*	*From not-for-profit eye facilities No. (%)*	*Number of NICU/ SNCU*	*From public eye facilities No. (%)*	*From not-for-profit eye facilities No. (%)*	*Number of NICU/ SNCU No.*	*Total NICU/ SNUC No.*
None	3 (17)	4 (33)	0	18 (10)	5 (42)	0	0
1 unit	13 (72)	5 (42)	18	0	4 (42)	4	22
2 units	2 (11)	1 (8)	6	0	0	0	6
3 units	0	2 (17)	6	0	0	0	6
5 units	0	0	0	0	1 (8)	5	5
9 units	0	0	0	0	1 (8)	9	9
10 units	0	0	0	0	1 (8)	10	10
Total	18 (10)	12 (10)	30	18	12 (100)	28	58

NICU: Neonatal Intensive Care Unit; SNCU: Special neonatal care unit.

(*n*=15) (mean 4.5, range 1-12 compared with mean 1.1, range 1-2). Twenty four of the 28 private NICUs were visited by just three not-for-profit eye-care facilities.

Approaches to screening and treatment: All facilities had indirect ophthalmoscopes and they used a range of different approaches to screen for ROP, often in combination. Over half (54%) reported that ophthalmologists made regular weekly visits to screen in the NICU, and half examined infants in the eye facility. In 29% of cases, an ophthalmologist visited the NICU when requested by NICU staff, and screening by a technician using a RetCam was reported by two providers (8%). In 17 facilities, screening was only by indirect ophthalmoscopy; one used only a RetCam, and five used a combination. Public sector facilities were more likely to undertake regular screening in the NICU than not-for profit facilities (88.9% *vs*. 33.3%, respectively; *P*<0.01), and specialist eye hospitals were more likely to screen using a RetCam (54.5% *vs*. 0%, respectively; *P*=0.002).

Twenty facilities had a functional laser, and peripheral laser photocoagulation was the first-line treatment of choice in 79%, with one each using cryotherapy or an Anti-VEGF preparation. Data were missing on the first-line treatment preferred for three facilities. Again, treatment was provided in a range of locations, with some treating in more than one location. The most frequent location was in the operating theatre of the eye-care facility (54%) and 42% provided treatment in the NICU. Staff in one facility treated in the operating theatre of the maternity hospital where the NICU was located. Staff working in specialist eye hospitals were more likely to treated in the NICU than those in public facilities (*P*=0.04). There were no significant differences between type of eye-care facility by treatment method.

Half the facilities had adequate resources to undertake complex vitreoretinal surgery for infants with Stage 4 or 5 ROP, and the other 50% referred these infants. Vitreoretinal surgery was more frequently available in specialist eye hospitals than general hospitals (91% *vs*. 15%, respectively; *P*<0.001), and in not-for-profit facilities than public (89% *vs*. 27%, respectively; *P*=0.003).

Infants screened and treated: Of the 24 facilities with services for ROP, 19 were able to provide data on the number of infants screened and 15 provided data on the number of infants treated, but not all could provide all the data requested. 42% of the 19 facilities providing data on screening screened less than 100 infants annually, and six screened more than 300 annually. Overall, an average of 243 (range 2-800) infants were screened annually. Not-for-profit facilities screened a larger number of infants (mean 310, range 42-800 per annum) than those in the public sector (mean 183, range 2-600). No data were provided by facilities in smaller cities; those in larger cities screened 245 (range 12-800) infants annually.

Five of the 15 facilities providing data on treatment treated ≥30 infants annually with three treating ≥10 each year. The mean overall number of infants treated annually was 39 (range 1-200). No data were provided by eye departments in multispecialty institutions nor by facilities in smaller cities. Speciality eye hospitals treated an

average of 55.4 (range 10-200) infants annually. Public and private sector facilities treated similar average (range) numbers annually, (32.5 (12-1000) and 40.5, (1-200), respectively).

DISCUSSION

This study provides a snap-shot of services provided for ROP by eye-care training institutions in the largest cities in India. Care is required in interpreting the findings, as the study was not comprehensive nor were the facilities selected so as to be representative. However, the level of services provided for ROP is likely to be lower in non-teaching institutions outside the large cities included in the study with a few notable exceptions. For example, several large specialist eye hospitals in the not-for-profit sector run excellent programmes for ROP and they were not included as they are located in smaller cities. However, most of the large public NICUs are located in major cities and the study provides insights into the screening and treatment provided by some of the largest training institutions in each city.

The findings suggest that eye care facilities in larger cities were more likely to have services for ROP than those in smaller cities, which may reflect greater awareness of ROP although this can only be conjectured. Eye-care facilities in larger cities were also more likely to monitor the number of babies screened and treated, which is to be encouraged. Facilities in the not-for-profit sector visited a larger number of NICU/SNCU than government training institutions, and showed greater flexibility, providing services in government as well as private NICU/SNCU. This may change in the future as public-private partnerships become more established [7]. Not-for-profit specialist eye care facilities were also more likely to comply with NNFI guidelines and international norms regarding where screening for ROP takes place *i.e.*, in the NICU/SNCU, and were also more likely to treat sight-threatening ROP in the NICU. Only two facilities had trained technicians who visited NICU/SNCU to screen using RetCam digital imaging which may reflect the cost of RetCams and/or that technicians are not permitted to screen. Providing screening and treatment within the NICU/SNCU is to be encouraged, as it leads to more efficient and effective programmes, as a higher proportion of eligible infants are likely to be screened, and screening and treatment are more likely to occur at the right time.

Blencowe, *et al*. [8] estimate that among the 3.5 million preterm births annually in India, almost 100,000 survive neonatal care each year and require screening for ROP i.e. 80 per million population per year. However, this estimate assumes that 30% of preterm infants have access to neonatal care which is likely to be far higher in many cities. The total population of the cities included in this study is approximately 77 million, which suggests there at least 6,150 infants annually who require screening for ROP. This again is an under-estimate as it does not include sick infants who fall outside the birthweight and gestational age screening criteria recommended by NNFI. In this study, the average number screened each year from the 19 institutions providing data was 240, suggesting that approximately 4,560 infants are being screened annually i.e. approximately 74% of the need is being met. It also seems highly likely that the 11 cities included this study would have more than 58 NICUs/SNCUs, the total number visited by the 24 eye care facilities who were screening in this study. More needs to be done to improve the coverage and efficiency of programs so that all infants at risk are screened. One approach would be to build the capacity of training institutions who are not yet providing services for ROP.

The vast majority of eye-care facilities use peripheral laser photocoagulation as the treatment of choice, with only one using cryotherapy and another using intravitreal injection of anti-VEGF agents. Four institutions providing a screening service lacked a laser. It is imperative that all facilities who are screening for ROP have access to a suitable laser (*i.e.*, delivered via indirect ophthalmoscopy) and personnel to treat sight threatening disease, as laser remains the treatment of choice and is highly effective in skilled hands.

Specialist eye-care facilities in the not-for-profit sector were also more likely to be able to provide vitreoretinal surgery for infants with advanced ROP than facilities in the public sector. These capabilities need to be expanded in the government sector, perhaps through the identification and strengthening of one tertiary-level referral centre per State. Facilities for the management of advanced ROP will continue to be required for the foreseeable future as neonatal care continues to expand in India, but the emphasis must remain on improving the quality of neonatal care to reduce the incidence of sight threatening ROP, and on the expansion of regular and effective screening programmes with prompt treatment.

A limitation of the study was that data were not collected on the number of NICU/SNCU in the cities included in the study, and so it was not possible to accurately determine the proportion with ROP services. As a follow up to this study, it would be important to map all NICU/SNCU in each city by sector, and ascertain the proportion where services for screening and treatment are being provided, by sector. The information collected from this study could then be used to match potential eye-care facilities to units which do not yet have ROP

WHAT IS ALREADY KNOWN?

- No information is available on services for ROP provided by training institutions in the major cities in India.

WHAT THIS STUDY ADDS?

- Most training institutions in the major cities in India are providing some services for ROP, but services need to expand in order to meet the increasing need, and be compliant with National guidelines.

services. Other limitations are that data were not collected on the indications used for screening, to ascertain whether these complied with NNFI recommendations; NICU/SNCU were not visited and records of the number of babies screened and treated were not reviewed to corroborate the findings.

A further avenue for study would be to evaluate the ROP services being provided in terms of quality of care, sustainability, scalability, cost effectiveness, efficiency and acceptability.

One-in-five tertiary-level eye-care training institutions in the largest cities in India did not provide a service for ROP, and most with a service only included one NICU/SNCU. Increasing the coverage of screening and treatment of sight-threatening ROP in all units caring for preterm infants will require political commitment, leadership and policies that lead to greater allocation of resources, and systems for monitoring the coverage and outcomes of initiatives [9]. As provision of newborn care continues to expand and an even greater number of preterm infants at risk of ROP survive, the challenges will increase in the future. Screening coverage could be expanded through the use of telemedicine [10], and new imaging systems are becoming available which would allow members of the neonatal team to take and even interpret retinal images [11].

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