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Review Paper

Not taking Standard Precautions in Retinopathy of Prematurity (ROP): Cost Hospital/Doctors Damages in Crore

¹Dr.Mukesh Yadav, M.D., MBA (HCA), PGDHO&QM, PGDHR, ²Dr.Pooja Rastogi, M.D.

Abstract

This is fourth case in the kitty of more than one crore compensation in medical negligence cases in India pronounced by the Hon'ble SC on 1st July 2015 i.e. on the Doctor's Day.

This case highlighted and applied various doctrines like: vicarious liability, importance of proper and relevant record keeping, timely referral and standard precautions and method of calculation of amount of compensation and factors relevant for computation of compensation. Two pediatrics doctors were held negligent in this case and Government of Tamil Nadu and Director General of Health Services were also held liable for compensation by applying the doctrine of apportionment of liability and vicarious liability.

This paper deals with critical review of decision of the Hon'ble SC in V. Krishnakumar vs. State of Tamil Nadu & Ors., 2015, its impact on the healthcare scenario in India and other stakeholders. Various doctrines relevant to the cases of medical negligence have been discussed to create awareness and understanding the factors responsible for high cost of compensation. Thus, help in sensitizing healthcare professionals about the issue of medical negligence and their prevention in future.

Key Words: Standard Precaution, Pediatrics, Ophthalmology, Retinopathy of Prematurity, Blindness, Screening Test, Vicarious Liability, Jointly and Severally, Apportionment of Liability

Introduction:

Cases of medical negligence with increased amount of claim for compensation have been increasing day by day in India. It can be attributed to many variables, important of which includes: increased cost of healthcare, increased cost of medicines, increased cost of medical education and increased cost of litigation along with inflation rate.

Impact of non information about consequences of ROP and mandatory screening for ROP, and future consequences on patient and parents have been taken consideration by the SC. Various doctrines like vicarious liability and apportionment of liability and compensation in a case of composite negligence has been applied in this case.

Corresponding Author:

¹Professor & Head

Department of Forensic Medicine & Toxicology,
Rama Medical College, Hapur, U.P.

Email: drmukesh65@yahoo.co.in

Mob.No.8527063514

²Professor & Head

School of Medical Sciences & Research
Sharda University, Greater Noida, U.P.

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V. Krishnakumar vs. State of Tamil Nadu & Ors., 2015 [1] is the Fourth case in the series in which more than one crore compensation has been awarded by the Indian courts, two of them in the year 2015 including this case. Highest compensation in a medical negligence case of Dr.Kunal Saha [2] in which more than 11 crore compensation has been awarded included interest on claim.

This trend of high amount of compensation is alarming as for as Indian context are considered seeing proportion of poor population in India. Recent Annual survey reports of NSSO [3] highlighted the impact of high cost of healthcare and role of private healthcare service providers and government hospitals.

High cost of compensation will certainly leads to increase cost of indemnity insurance premium, defensive medicine practices and unethical practices of unnecessary investigations and procedures and referral and consultations.

Discussion:

Background of the case:

Two Civil Appeals have been preferred before the SC against the judgment of National Consumer Disputes Redressal Commission (NCDRC) rendering a finding of medical negligence against the State of Tamil Nadu, its

Government Hospital and two Government Doctors and awarding a sum of Rs.500000/- to V. Krishnakumar.

Civil Appeal was preferred by V. Krishnakumar for enhancement of the amount of compensation. Another Civil Appeal was preferred by the State of Tamil Nadu and another against the judgment of the NCDRC dated 24th May 2009. As facts of both the appeals were same, SC Bench disposed both the appeals by the common judgment dated 1st July 2015. [Para 1] [1]

Facts of the Case:

On 30.8.1996, V. Krishnakumar's wife Laxmi was admitted in Government Hospital for Women and Children, Egmore, Chennai. Against the normal gestation period of 38 to 40 weeks, she delivered a premature female baby in the 29th week of pregnancy. The baby weighed only 1250 grams at birth. The infant was placed in an incubator in intensive care unit for about 25 days. The mother and the baby were discharged on 23.9.1996.

Relevant Fact and Issue:

SC Bench observed that a fact which is relevant to the issue was, that the baby was administered 90-100% oxygen at the time of birth and underwent blood exchange transfusion a week after birth. The baby had apneic spells during the first 10 days of her life.

Parties to the Dispute:

Appellant No1: P-1: V. Krishnakumar (Husband of the Patient Laxmi and Father of the Minor (Sharanya) who suffered blindness due to ROP as a result of alleged negligence of not warning the mandatory screening test for ROP.

Respondents Parties:

1. **Respondent No.1: R-1:** Director, Government Hospital for Women and Children, Egmore, Chennai
2. **Respondent No.2: R-2:** State of Tamil Nadu under the Department of Health
3. **Respondent No.3: R-3:** Dr.S. Gopaul, Neo-paediatrician (Treating Doctor) and Chief of Neo Natology Unit of the Hospital
4. **Respondent No.4: R-4:** Dr.Duraiswamy of the Neo Natology Unit of the Hospital. [Para 2] [1]

Important Observations of the SC:

The baby and the mother visited the hospital on 30.10.1996 at the chronological age of 9 weeks. **Follow up treatment** was administered at the home of the appellant by R-4, during home visits. The baby was under his care from 4 weeks to 13 weeks of chronological age.

Apparently, the only advice given by R-4 was to keep the baby isolated and confined to the four walls of the sterile room so that she could be protected from infection. [Para 3]

SC Bench emphasized that what was completely overlooked was a well known medical phenomenon that a premature baby who has been administered supplemental oxygen and has been given blood transfusion is prone to a higher risk of a disease known as the Retinopathy of Prematurity (ROP), which, in the usual course of advancement makes a child blind.

The R-3, who was also a Government Doctor, checked up the baby at his private clinic at Purassaiwakkam, Chennai when the baby was 14-15 weeks of chronological age also did not suggest a check up for ROP. [Para 3]

Issue of ROP and Blindness:

Division Bench of the SC observed that one thing was clear about the disease, and, that the disease occurs in infants who are prematurely born and who have been administered oxygen and blood transfusion upon birth and further, that if detected early enough, it can be prevented. It is said that prematurity is one of the most common causes of blindness and is caused by an initial constriction and then rapid growth of blood vessels in the retina. When the blood vessels leak, they cause scarring. These scars can later shrink and pull on the retina, sometimes detaching it. The disease advances in severity through **five stages - 1, 2, 3, 4 and 5 (5 being terminal stage)**.

Medical literature suggests that stage 3 can be treated by Laser or Cryotherapy treatment in order to eliminate the abnormal vessels. Even in stage 4, in some cases, the central retina or macula remains intact thereby keeping intact the central vision.

When the disease is allowed to progress to stage 5, there is a total detachment and the retina becomes funnel shaped leading to blindness. There is ample medical literature on the subject.

Review of Literature:

Some material relevant to the need for check up for ROP for an infant is:

"All infants with a birth weight less than 1500 gms or gestational age less than 32 weeks are required to be screened for ROP." [1]

SC Bench concluded that applying either parameter, whether weight or gestational age, the child ought to have been screened. As stated earlier, the child was 1250 gms at birth and born after 29 weeks of pregnancy, thus

making her a high risk candidate for ROP. [Para 4]

It was undisputed that the relationship of birth weight and gestational age to ROP as reproduced in NCDRC's order is as follows:

"Most ROP is seen in very low-birth weight infants, and the incidence is inversely related to birth weight and gestational age. About 70-80% of infants with birth weight less than 1000 gms show acute changes, whereas above 1500 gms birth weight the frequency falls to less than 10%." [Para 5] [1]

SC emphasized that again, it seems that the child in question was clearly not in the category where the frequency was less than 10% since the baby was below 1500 gms. In fact, it is observed by the NCDRC in its order that the discipline of medicine reveals that all infants who had undergone less than 29 weeks of gestation or weigh less than 1300 gms should be examined regardless of whether they have been administered oxygen or not. It is further observed that ROP is a visually devastating disease that often can be treated successfully if it is diagnosed in time. [Para 6] The need for a medical checkup for the infant in question was not seriously disputed by the respondents. [Para 7] [1]

Defense Argument:

The main defence of the respondents to the complaint of negligence against the appellant's claim for compensation was that at the time of delivery and management, no deformities were manifested and the complainant was given proper advice, which was not followed.

Issue of Discharge Summary:

It was argued on behalf of the respondent that they had taken sufficient precautions, even against ROP by mentioning in the **discharge summary** as follows:

"Mother confident; Informed about alarm signs; 1) to continue breast feeding 2) To attend post natal O.P. on Tuesday." [Para 8] [1]

It must, however, be noted that the discharge summary shows that the above writing was in the nature of a scrawl in the corner of the discharge summary and we are in agreement with the finding of the NCDRC that the said remarks are only a hastily written general warning and nothing more. After a stay of 25 days in the hospital, **it was for the hospital to give a clear indication as to what was to be done regarding all possible dangers which a baby in these circumstances faces.** It is obvious that it did not occur to the respondents to advise the appellant **that the baby is required to be seen**

by a paediatric ophthalmologist since there was a possibility of occurrence of ROP to avert permanent blindness. This discharge summary **neither discloses a warning to the infant's parents that the infant might develop ROP** against which certain precautions must be taken, nor any signs that the Doctors were themselves cautious of the dangers of development of ROP. [Para 9]

Division Bench observed that we are not prepared to infer from '**Informed about alarms signs**' that the parents were cautioned about ROP in this case. [Para 9] [1]

Bench find it unfortunate that the respondents at one stage took a stand that the appellant did not follow up properly by not attending on a Tuesday but claiming that the mother attended on a Wednesday and even contesting the fact that she attended on a Wednesday. It appears like a desperate attempt to cover up the gross negligence in not examining the child for the onset of ROP, which is a **standard precaution** for a well known condition in such a case. In fact, it is not disputed that the R-3 attended to and examined the baby at his private clinic when the baby was 14-15 weeks and even then did not take any step to investigate into the onset of ROP. The R-4 also visited the appellant to check up the baby at the home of the appellant and there are prescriptions issued by the R-4, which suggests that the baby was indeed under his care from 4 weeks to 13 weeks. [Para 9] [1]

Medical Opinion:

Opinion of Medical Board of AIIMS, New Delhi

The NCDRC has relied on the report dated 21.8.2007 of the All India Institute of Medical Sciences (AIIMS), New Delhi. In pursuance of the order of the NCDRC, a medical board was constituted by AIIMS consisting of five members, of which, four were ophthalmological specialists. The board has given the following opinion:

"A premature infant is not born with Retinopathy of Prematurity (ROP), the retina though immature is normal for this age. The ROP usually starts developing 2-4 weeks after birth when it is mandatory to do the first screening of the child. The **current guidelines** are to examine and screen the babies with birth weight <1500 gm and <32 weeks gestational age, starting at 31 weeks post-conceptual age (PAC) or 4 weeks after birth whichever is later. Around a decade ago, the guidelines in general were the same and the premature babies were first examined at 31-33 weeks post-conceptual age or 2-6 weeks after birth. There is a general

agreement on these above guidelines on a national and international level. The Table No.1 explains some **authoritative resources and guidelines published in national and international literature** especially over the last

decade. However, in spite of ongoing interest world over in **screening and management of ROP** and advancing knowledge, it may not be possible to exactly predict which premature baby will develop ROP and to what extent and why."

Table No.1 Review of literature of ROP Screening Guidelines			
Year	Source	First Screening	Who to screen?
2006	American Academy of Pediatrics et al.	31 wks PCA or 4 wks after birth whichever later	<1500gms birth weight or <32 wks GA or higher
2003	Jalali S et al. Indian J Ophthalmology	31 wks PCA or 3-4 wks after birth whichever earlier	<1500g birth weight or <32 wks GA or higher
2003	Azad et al. JIMA	32 wks PCA or 4-5 wks after birth- whichever earlier	<1500g birth weight or <32 wks GA or higher
2002	Aggarwal R et. Al Indian J. Pediatrics	32 wks PCA or 4-6 wks after birth whichever earlier	<1500 gm birth weight or <32 wks GA
1997	American Academy of Paediatrics et al.	31-33 wks PCA or 4-6 wks after birth	<1500 gm birth weight or <28 wks GA or higher
1996	Maheshwari R et al. National Med. J. India	32 wks PCA or 2 wks after birth whichever is earlier	<1500 gm birth weight or <35 wks GA or O2>24 hrs
1988	Cryotherapy ROP Group	4-6 wks after birth	<1250 gms birth weight
Source: Para 10 [1]			

ROP screening guidelines

SC observed that one thing this report reveals clearly and that is that in the present case the **onset of ROP was reasonably foreseeable**. Division Bench said this because it was well known that if a particular danger could not reasonably have been anticipated it cannot be said that a person has acted negligently, because a reasonable man does not take precautions against unforeseeable circumstances. Though it was fairly suggested to the contrary on behalf of the respondents, there is nothing to indicate that the disease of ROP and its occurrence was not known to the medical profession in the year 1996.

This is important because **whether the consequences were foreseeable or not must be measured with reference to knowledge at the date of the alleged negligence, not with hindsight**. We are thus satisfied that we are not looking at the 1996 accident with 2007 spectacles. [2]

It is obvious from the report **that ROP starts developing 2 to 4 weeks after birth when it is mandatory to do the first screening of the child**. The baby in question was admitted for a period of 25 days and there was no reason why the mandatory screening, which is an accepted practice, was not done. The report of the AIIMS states that **'it may not be possible to exactly predict which premature baby will develop ROP and to what extent and why'**.

This in view of the Division Bench of the SC underscores the need for a checkup in all such cases. In fact, the screening was never done. There is no evidence whatsoever to suggest to the contrary.

Opinion of Pediatrician from Mumbai:

SC emphasized that it appears from the evidence that the ROP was discovered when the appellant went to Mumbai for a personal matter and took his daughter to a Pediatrician, Dr.Rajiv Khamdar for giving DPT shots when she was 4½ months. That Doctor, suspected ROP on an examination with naked eye even without knowing the baby's history.

Opinion of Ophthalmologists:

But, obviously R-3 and R-4 the **Doctors entrusted with the care of the child did not detect any such thing at any time**. The helpless parents, after detection got the baby's eyes checked by having the baby examined by several doctors at several places.

Traumatized and shocked, they rushed to Puttaparthi for the blessings of Shri Satya Sai Baba and the baby was anesthesiologically examined by Dr.Deepak Khosla, Consultant, Department of Ophthalmology, Baba Super Specialty Hospital at Puttaparthi.

Dr.Khosla did not take up the case since the ROP had reached stage 5. After coming back from Puttaparthi, the baby was examined by Dr.Tarun Sharma alongwith the retinal team of Shankar Netralaya, who were also of the **same opinion**.

The parents apparently took the baby to Dr.Namperumal Swamy of Arvind Hospital, Madurai, who advised against surgery, stating that the baby's condition was unfavourable for surgery. The appellant then learnt of Dr.Michael Tresse, a renowned expert in Retinopathy treatment for babies in the United States.

Opinion from USA:

Father of the baby obtained a reference from Dr.Badrinath, Chief of Shankar Netralaya and took his only child to the United States hoping for some ray of light. **The appellant incurred enormous expenses for surgery in the United States but to no avail.** [Para 11] [1]

SC Approved NCDRC Judgment:

Having given anxious consideration to the matter, Division Bench of SC find that no fault can be found with the findings of the NCDRC which has given an unequivocal finding that at no stage, the appellant was warned or told about the possibility of occurrence of ROP by the respondents even though it was their **duty to do so.**

SC further observed that neither did they explain anywhere in their affidavit that they warned of the possibility of the occurrence of ROP knowing fully well that the chances of such occurrence existed and **that this constituted a gross deficiency in service,** nor did they refer to a **pediatric ophthalmologist.**

Bench observed that further it may be noted that R-3 & R-4 have not appealed to the S C against the judgment of the NCDRC and have thus accepted the finding of medical negligence against them. [Para 12] [1]

Deficiency in Service

In the circumstances, SC Division Bench agreed with the findings of the NCDRC [6] **that the respondents were negligent in their duty and were deficient in their services in not screening the child between 2 to 4 weeks after birth when it is mandatory to do so and especially since the child was under their care. Thus, the negligence began under the supervision of the Hospital i.e. R-2.**

Issue of Private Practice:

The R-3 and R-4, who checked the baby at his private clinic and at the appellant's home, respectively, were also negligent in not advising screening for ROP. It is pertinent to note that R-3 and R-4 carried on their own private practice while being in the employment of R-2, which was **a violation of their terms of service.** [Para 13]

Bench of SC find from the impugned order of the NCDRC [R-4] that the compensation awarded by that Forum is directed to be paid

only by R-1 and R-3 i.e. the State of Tamil Nadu and Dr.S. Gopaul, Neo-Pediatrician, Government Hospital for Women & Children, Egmore, Chennai. No reason has been assigned by the Forum for relieving R-2 and R-4. Dr.Duraiswami, Neo Natology Unit, Government Hospital for Women & Children, Egmore, Chennai, who also treated Sharanya during the course of his visits to the house of the appellant. [Para 26]

Issue of Vicarious Liability

SC Bench clarified that it is settled law that the hospital is vicariously liable for the acts of its doctors vide Savita Garg vs. National Heart Institute, (2004) [4], also followed in Balram Prasad's case [2]. Similarly in Achutrao Haribhau Khodwa vs. State of Maharashtra, (1996) [5] the SC unequivocally held that the state would be vicariously liable for the damages which may become payable on account of negligence of its doctors or other employees.

Bench added that by the same measure, it is not possible to absolve R-1, the State of Tamil Nadu, which establishes and administers such hospitals through its Department of Health, from its liability. [Para 27] [1]

Apportionment of Liability among respondents:

In the circumstances, Bench considered it appropriate to apportion the liability of Rs.13800000/- among the respondents and shall be paid by R-1 to R-4 **within three months from 1st July 2015** otherwise the said sum would attract a penal interest at the rate of 18% p.a. [Para 28]

Similarly, Bench directed that the amount of Rs.4287921/- in lieu of **past medical expenses,** shall be apportioned among all four respondents jointly and severally with interest of 6% p.a. from 27th May 2009.[6] [Para 29] [1]

Summary and Conclusions:

Not informing important side effects or not referring to the concerned specialist for mandatory screening for ROP amount to deficiency in service and medical negligence on the part of treating doctor. Court takes inflation and future cost of treatment, financial hardship faced by the parents and mental suffering, etc. in computing the quantum of compensation in such a case of medical negligence. SC held Government of Tamil Nadu and the Director of Health Department vicariously liable for damage caused to the patient due to negligence of its employee and apportionment of liability among all four respondents.

There is need for keeping updates about development in the field of medicine by attending CMEs, conference and workshops in concerned specialty to avoid case of such medical negligence on the part of doctors.

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