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Original Article

Low Birth Weight and Preterm Neonates: Can they be Managed at Home by Mother and a Trained Village Health Worker?

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OBJECTIVE:

Observations on a cohort of neonates in the preintervention year of the field trial of home-based neonatal care (HBNC) in rural Gadchiroli, India, showed that preterm birth and low birth weight (LBW), <2500 g, constituted the most important risk factors. Owing to a limited access to hospital care, most neonates were managed at home in the subsequent intervention years. The objective of this paper is to evaluate the feasibility and effectiveness of managing LBW and preterm neonates in home setting.

DESIGN:

We retrospectively analyzed data from the intervention arm (39 villages) in the HBNC trial. Feasibility was assessed by coverage and by quality (19 indicators) of care. Effectiveness was evaluated by change in case fatality (CF) and in the incidence of comorbidities in LBW or preterm neonates by comparing the preintervention year (1995 to 1996) with the intervention years (1996 to 2003).

RESULTS:

During 1996 to 2003, total 5919 live births occurred in the intervention villages, out of whom 5510 (93%) received HBNC. These included 2015 LBW neonates and 533 preterm neonates, out of whom 97% received only home-based care. The coverage and quality of interventions assessed on 19 indicators was 80.5%. The CF in LBW neonates declined by 58% (from 11.3 to 4.7%, $p<0.001$), and in preterm neonates, by 69.5% (from 33.3 to 10.2%, $p<0.0001$). Incidence of the major comorbidities, viz., sepsis, asphyxia, hypothermia and feeding problems, declined significantly.

Preterm-LBW neonates without sepsis (270) received only supportive care — CF in them decreased from 28.2 to 11.5% ($p<0.01$), and those with sepsis (53) received supportive care and antibiotics — CF in them decreased from 61 to 13.2% ($p<0.005$). Supportive care contributed 75% and treatment with antibiotics 25% in the total averted deaths in preterm-LBW neonates. The intrauterine growth restriction (IUGR)-LBW neonates without sepsis (1409) received only supportive care — the CF was unchanged, and 181 with sepsis received supportive care and antibiotics — the CF decreased from 18.4 to 8.8% ($p<0.05$). Treatment with antibiotics explained entire reduction in mortality in IUGR neonates. In total, 55 deaths in LBW neonates were averted by supportive care and 35 by the treatment with antibiotics.

CONCLUSIONS:

Home-based management of LBW and the preterm neonates is feasible and effective. It remarkably improved survival by preventing comorbidities, by supportive care, and by treating infections.
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INTRODUCTION

Low birth weight (LBW), defined as a birth weight <2500 g, is indisputably a very important indirect cause of death in neonates the world over. Globally, between 40 and 80% of neonatal deaths occur among LBW neonates. The World Health Organization estimates that 16% of neonates, or nearly 20 million, are born LBW each year. The highest incidence is observed in South Asia, where an estimated 31% of neonates are born LBW, contributing 11 million, a little more than half, of the world's LBW neonates.[1]

LBW is caused by intrauterine growth restriction (IUGR), short gestation or both. The incidence of preterm birth (<37 completed weeks of gestation) is fairly similar worldwide, generally ranging between 7 and 16% of total births and, according to WHO estimates, is the direct cause of 24% of neonatal deaths. In South Asia, IUGR is responsible for nearly two-thirds of all LBW neonates.[1]

Attempts to prevent LBW or preterm births in populations have been largely ineffective. This is one of the most challenging and frustrating problems in public health. Kramer[2,3] and, more recently, Ramakrishnan and Neufeld,[4] have reviewed the results of various interventions, including food and micronutrient supplements. In spite of occasional promising results, such as high-energy supplementation in the Gambia trial,[5] large-scale trials and meta-analyses have shown very little effect on the incidence of LBW.

LBW and preterm birth were major problems in Gadchiroli. A cohort of 763 neonates born in 39 villages was studied in the preintervention year (1995 to 1996) of the field trial of home-based neonatal care (HBNC) in Gadchiroli, India.[6,7] The distribution of neonates by birth weight and period of gestation in the preintervention year, percent case fatality (CF) and the proportion of deaths contributed are presented in Table 1. Nearly 42% neonates were LBW, with a mean 11.3% CF. Of the total neonatal deaths, 90% occurred in the LBW neonates. The 9.8% of neonates were born preterm, experienced high (33%) CF and they accounted for 62.5% of total neonatal deaths. Table 1 also shows that the CF in neonates with birth weight >2500 g was 0.2%, in IUGR neonates it was 4.4% and in preterm neonates it was 40.3%.

The estimated population attributable risk (PAR) of death in this cohort was 0.74 for preterm birth and 0.55 for IUGR. However, analysis of deaths by associated morbidities also revealed that CF was low in LBW or preterm neonates without other associated morbidities. The CF progressively and steeply increased with the number of comorbidities, viz., sepsis, asphyxia, hypothermia and feeding problems, complicating the LBW or preterm birth.[8] We also estimated that PAR for sepsis was 0.55; for asphyxia 0.35; for hypothermia 0.08 and for feeding problems 0.04. Based on this analysis and practical common sense, we proposed that if LBW and preterm births cannot be prevented, an alternative approach could be to manage them by preventing and treating comorbidities. We hypothesized that by using this approach, the HBNC would substantially improve neonatal survival including the survival of LBW or preterm neonates.[8]

The objective of this paper is to evaluate the feasibility and effectiveness of HBNC in the management of LBW or preterm neonates in the Gadchiroli field trial, and to explain the effect.

Table 1 The Baseline Incidence and CF in Different Birth Weight and Gestation Strata and Percent of Total Deaths (1995–1996, $n = 763$, deaths = 40)

Characteristic	% Incidence	% CF	Proportion of total deaths (%)
(a) Birth weight (g)[$]			
≥2500	54.7	0.2	2.5
< 2500	41.9	11.3	90.0
2000–2499	32.2	3.7	22.5
1500–1999	8.0	29.5	45.0
<1500	1.7	69.2	22.5
Not recorded	3.4	11.5	7.5
Preterm LBW*,[†]	8.6	40.3	62.5
IUGR[‡] LBW[†]	34.9	4.4	27.5
(b) Gestation (weeks)[$]			
≥37	88.2	2.1	35.0
<37	9.8	33.3	62.5
35–36	6.0	21.7	25.0
33–34	2.4	33.3	15.0
<33	1.4	81.8	22.5
Not recorded	2.0	6.7	2.5
Preterm ≥2500 g[†]	1.4	0.0	0.0
Preterm <2500 g[†]	8.6	40.3	62.5

[$]a and b are the two classifications of the same 763 neonates.
*Low birth weight.
[†]Denominator 725 neonates because of missing gestation or birth weight data in some.
[‡]Intrauterine growth restriction.

METHODS

The area, study design, data collection, preintervention morbidities and the HBNC interventions have been described elsewhere.[7–13] Here we shall only describe the relevant salient points.

Home Visiting

Resident women with 5 to 10 years of school education were selected, usually one each in 39 intervention villages (total population 39,312) and trained as village health workers (VHWs). Each VHW registered the pregnant women in her village, usually in the 4th month of pregnancy. Using a cultural calendar, she determined the date of the onset of last menstruation by asking the history, and calculated the expected date of delivery. Most of the women delivered at home, with delivery conducted by traditional birth attendants (TBA). The VHW also attended the delivery. On the day of birth, she determined the period of gestation based on the expected date of delivery that she had earlier calculated and recorded. Less than 37 weeks of gestation was called preterm birth. She recorded all information on a printed mother–neonate record.

The VHW weighed the newborn, usually within 1 to 6 hours after birth. When she was not present at birth, she visited and weighed the baby almost always within 24 hours. She used a spring balance (Salter) of 0 to 5 kg range with a discriminatory power of 25 g. The instrument was adjusted and corrected for the ''zero error'' every time the weight was measured and was tested for accuracy once in 3 months by weighing the standard weights. In case of hospital delivery, she used the birth weight recorded in hospital.

Based on the data on a cohort of 763 neonates in the preintervention year, we identified the presence of any one or more of the following as predictors of the risk of neonatal death: birth weight <2000 g, gestation <37 weeks, or baby not taking feeds on the first day.[13] Such high-risk neonates received more care from VHWs.

The VHW revisited the mother and neonate on days 2, 3, 5, 7, 15, 21 and 28. The visits to ''high-risk'' neonates were increased starting in 1999, with additional visits on days 4, 6, 9, 12, 18 and 24. The baby was weighed every week, and finally on day 28. The

total weight gain during the neonatal period was calculated from these observations. Weight gain <300 g during the neonatal period was defined as ''inadequate weight gain'' because it predicted a risk of death in the 2nd month of life.[6]

Apart from the visits on the fixed days, VHWs made additional visits on any other day if the parents informed her that their baby was sick. The neonates were monitored by the VHWs until day 28 or until the mother and baby left the village or the baby died, whichever was earlier.

Interventions

The interventions for the management of LBW and preterm neonates are described in Box 1.

A supervisory physician (SBB) made visits to each village and to each neonate once in 15 days. He checked and corrected the records, the findings and the care given by the VHW and the family. From 2001, two VHWs were promoted to become field supervisors, with the physician overseeing their work.

From 1999, we introduced three additional measures: (1) The VHWs were introduced to kangaroo mother care[14] and were asked to teach it to mothers if the baby was hypothermic in spite of the HBNC. (2) An evaluation form was introduced to evaluate the HBNC care to each neonate, to be completed by the supervisor on the 28th day. (3) The VHWs were advised to refer to hospital (government hospital or SEARCH hospital) any neonate with sepsis who did not respond to treatment with antibiotics within 24 hours,

Box 1 Interventions in the home-based management

1. *Health education*: To all mothers
   - In group: All pregnant women in a village received 2 hours group health education, once in 4 months.
   - Individually (45 minutes) given by VHW using a flip chart twice during pregnancy, and on the second day after delivery.
   - The families with a high-risk neonate (preterm or birth weight <2000 g or difficulty in feeding on the first day) received a printed pamphlet and instructions for special care.
2. *Thermal care*:
   - Encouraged to use baby clothes and head wears.
   - All high-risk or the hypothermic neonates (axillary temperature <95°F), after initial warming by heated cloth, were covered in a blanket and put in sleeping bag.
   - Families were advised not to bathe high-risk or hypothermic neonates at least till 7th day.
   - The room was kept heated by fire.
3. *Breast feeding*:
   - Early initiation of breastfeeding within 6 hours after birth and exclusive breastfeeding.
   - The VHW educated mother by assisting in proper position, and attachment.
   - She managed breast problems (engorged breast or insufficient milk) by encouraging continued and repeated breastfeeding, and if necessary, by extracting breast milk and feeding with a spoon. VHWs were given a special traditional Indian spoon (*palade*), which has a long beak and facilitates feeding a baby who does not suck vigorously.
   - High-risk babies were given 2-hourly breast or spoon-feeding.
   - If mother had insufficient milk, breast milk was supplemented by boiled cow milk.
   - A breastfeeding monitoring form was introduced from the year 2000 for the babies who had problems in breastfeeding
4. *Prevention and management of infections*:
   - Hand washing by mothers.
   - Avoiding contact with persons with manifestations of infection.
   - Cleanliness of clothes and the hygiene in delivery room.
   - Putting tetracycline ointment in the eyes of every neonate at birth.
   - Cord care by keeping it clean, dry and applying gentian violet (1%).
   - Skin care — by keeping skin clean and dry.
   - Treating skin infections (pyoderma, intertrigo) with gentian violet.
5. *Management of neonatal sepsis*:
   - All neonates were monitored for the signs of sepsis. Sepsis was diagnosed by VHWs clinically, by using specific criteria.
   - Treatment with two antibiotics.
   - Supportive care (i.e. home visits, advice, thermal care and assistance in breast feeding)
   - If parents refused treatment with antibiotics, the baby received only supportive care.
6. *Vitamin K injection, 1 mg to all neonates*
7. *Referral*:

Those neonates whose feeding or temperature could not be maintained in spite of the home-based interventions, or those with sepsis who did not respond within 24 hours of starting antibiotics were to be referred to the hospital. However, it was up to the parents to act upon this.

any neonate who was persistently hypothermic in spite of home-based care or could not be breastfed or spoon-fed at home.

The interventions and the results up to March 31, 2003 are included in this analysis.

Analysis

The HBNC interventions were introduced incrementally from April 1996 and the full package from 1997. A computer algorithm applied clinical definitions to the data on newborns collected by the VHWs. The incidence of various comorbidities was estimated from these.

A separate vital statistics surveillance system, evaluated to be 98% complete, recorded all births and neonatal deaths in the 39 intervention and the 47 control villages.[9,11] The proportion of neonates born in 39 villages who were covered by the HBNC was estimated by comparing their number with the live births registered by this system. The estimated number of neonatal deaths was also based on the information collected by this system.

Figure 1 is a flow diagram showing different categories of neonates, and the type of care they received in different years of the trial.

Without our planning for it, a before–after and concurrent comparison was available in this trial. Some LBW and preterm neonates had received only supportive care, while some had received supportive care plus antibiotics (Figure 1). Their CF in the preintervention period (1995 to 1996) and in the intervention years (1996 to 2003) was available. To estimate the contribution of supportive measures (home visiting, breastfeeding, thermal care, Vitamin K, health education) and of the treatment with antibiotics in reducing CF, we compared the reduction in CF separately for the IUGR-LBW and the preterm-LBW neonates with sepsis and without sepsis, and estimated the absolute reduction in the CF. (a) The reduction in CF in neonates without sepsis or in neonates with clinical sepsis but who did not receive antibiotics was considered as the effect of the supportive measures. (b) The reduction in CF in LBW and preterm neonates with sepsis who received antibiotics was considered as the effect of supportive measures + antibiotics. The supportive measures being common in both groups, the net difference in the two reductions (a and b) was estimated as the effect of antibiotics.

χ^2 test with Yate's correction was used for estimation of significance.

Ethical Review

An external group of pediatricians, neonatologists and public health management experts advised and reviewed the study at three points in time and gave ethical clearance. Written consent was taken from the parents of the neonates with sepsis for home-based management.

RESULTS

In the preintervention year, 763 neonates in 39 villages were studied. Their distribution by birth weight and period of gestation

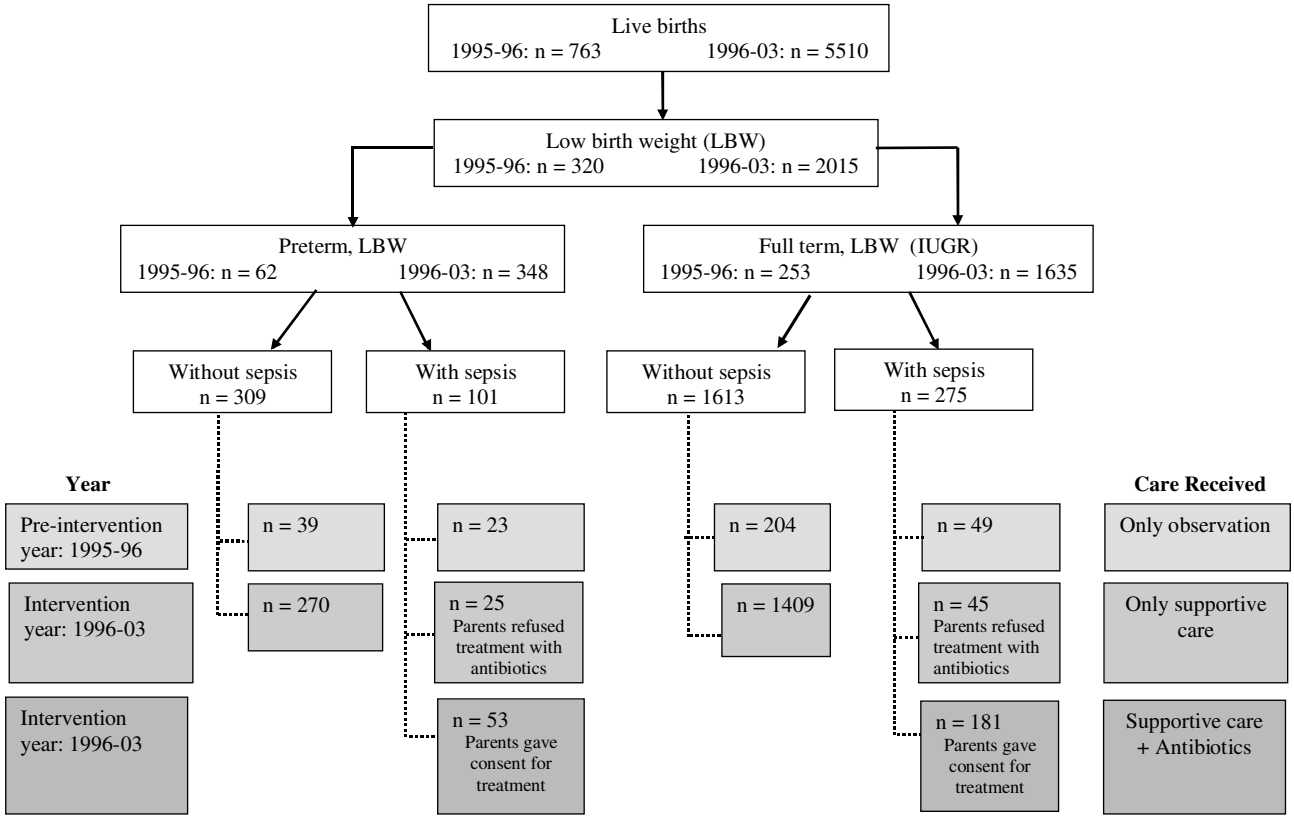

Figure 1. Low birth weight neonates and different types of care received (1995 to 2003).

and the CF in different strata are presented in Table 1. The number of neonates and their mean birth weight (in parenthesis) in different gestational groups was as follows: <32 weeks, 11 (1484 g); 33 to 34 weeks, 15 (1742 g); 35 to 36 weeks, 46 (2188 g); 37 to 38 weeks, 189 (2416 g); 39 to 40 weeks, 302 (2549 g) and >40 weeks, 162 (2613 g).

During the 7 years of intervention, 5919 live births occurred in the 39 intervention villages. The coverage of neonates by HBNC, the proportion detected LBW or preterm and the proportion of LBW or preterm who received home-based management are presented in Table 2. Out of the neonates born, 93% received HBNC, and 97% of the LBW/preterm babies were managed at home.

Number of neonates in different categories and the type of care they received in different years is presented in Figure 1.

Starting in 1999, the coverage and quality of home-based care to each neonate was evaluated on various indicators. The 19 indicators of the interventions or practices relevant to the management of LBW/preterm neonates and their coverage are presented in Table 3. Coverage of most of the indicators was in the range of 80 to 100%; it was <50% on three indicators: hand washing by mother, use of kangaroo care and advising referral.

The effectiveness of HBNC interventions in preventing LBW or preterm birth was evaluated by the change in the incidence of these two problems and has been reported elsewhere.[15] The incidence of preterm birth during different years from 1995 to 2003 remained almost constant, at nearly 10%. The incidence did not vary significantly in any of the gestation substrata as well.

Mean birth weight increased from 2472 g in 1995 to 1996 to 2584 g during 2000 to 2003 (+112 g), and the incidence of LBW decreased from 41.9 to 35.2%, a net decrease of 16%, which was highly significant. The change was distributed in all birth weight strata. The change in the mean birth weight and reduction in the incidence of LBW occurred mostly in neonates with IUGR. The incidence of IUGR (<2500 g and >37 weeks) decreased from 34.9% in 1995 to 1996 to 28.4% in 2000 to 2003.

The effect of home-based management on CF is presented in Tables 4 and 5. In preterm neonates (Table 4), the mean CF decreased by 69.5%, the highest decrease being in the 35 to 36 weeks group. In the <33 weeks group, in spite of a decrease, the CF remained high at 45%. In LBW neonates (Table 5), CF decreased by 58%. The decrease was most pronounced (67%) in neonates 2000 to 2499 g. The CF reached very low (1.2%), in neonates 2000 to 2499 g, but in the <1500 g group, it remained high, at 40%, in spite of a 42.2% decrease.

Further explanation of the improved survival of LBW/preterm neonates was sought in three effects: the incidence of comorbidities, the effect of managing sepsis with antibiotics and the effect of supportive care in LBW neonates.

Table 2 Coverage of Home-Based Care (1996–2003)

	No.	%
Total live births	5919	—
Home delivery	5387	91.0
Neonates provided home-based care	5510*	93.0
Birth weight measured	5454†	99.0
Identified as low birth weight	2015	36.9
Gestation determined	5429	98.5
Identified as preterm	533	9.8
LBW/preterm‡ neonates	2199	39.9
LBW/preterm‡ neonates hospitalized/received referral care	62	2.8
LBW/preterm‡ neonates received only home-based care	2137	97.2

*Some of the hospital born neonates returned to the villages and provided home-based care.
†Birth weight on hospital born neonates became available from hospital records.
‡Low birth weight or preterm or both.

Table 3 Coverage and Quality of Selected Home-Based Interventions for the Management of LBW/preterm* Neonates: 1999–2003 (total neonates = 3245, LBW/preterm* neonates = 1219)

Indicators of care or practice		%†
1.	Health education twice in pregnancy and once after delivery	95.5
2.	VHW‡ present at delivery	75.4
3.	Correct identification of high-risk§ baby	94.8
4.	Gave high-risk baby care pamphlet to family	95.8
5.	Proper thermal care by family	97.5
6.	Care for hypothermia properly provided by VHW	92.9
7(a).	Initiation of breastfeeding within 1 hour¶	60.7
7(b).	Initiation of breastfeeding within 6 hours¶	94.8
7(c).	Initiation of breastfeeding within 24 hours¶	99.9
8.	Feeding problems managed by VHW	95.4
9.	Babies not sucking advised referral by VHW	48.3
10.	Does mother hold baby properly while feeding?¶	98.1
11.	Did mother wash hands before feeding?¶	19.5
12.	Were mother's nails clipped?¶	95.8
13.	Did parents call VHW within 24 hours, when baby had health problems?¶	68.9
14.	Did VHW diagnose sepsis correctly?¶	94.0
15.	Did VHW treat sepsis correctly?¶	95.3
16.	If necessary‖, Kangaroo care method used?¶	12.5
17.	Weight measured each week for four weeks¶	86.9
18.	Weight increased by more than 300 g in 28 days¶	84.9
19.	Second month high-risk baby correctly diagnosed	84.4
	Mean of 19 indicators	80.5

*Low birth weight or preterm or both.
†The relevant denominator used varies for different indicators.
‡Village health worker.
§Preterm or <2000 gm or breastfeeding problem on the first day.
¶Among low birth weight or preterm or both cases.
‖If a LBW or preterm neonate was persistently hypothermic.

Table 4 Effect on CF in Different Gestational Groups: 1995–2003

Gestation period (weeks)	% CF						% Change 1995–1996 to 2000–2003	*p*
	1995–1996		1996–2000		2000–2003			
	(Deaths = 40, *n* = 763)		(Deaths = 78, *n* = 3165)		(Deaths = 50, *n* = 2345)			
Full term (≥37)	(14/673)	2.1	(43/2813)	1.5	(26/2083)	1.2	−40.0	NS
Preterm (<37)	(25/75)	33.3	(31/307)	10.1	(23/226)	10.2	−69.5	<0.0001
35–36	(10/46)	21.7	(9/218)	4.1	(5/162)	3.1	−85.8	<0.0002
33–34	(6/18)	33.3	(7/52)	13.5	(3/31)	9.7	−71.0	<0.05
<33	(9/11)	81.8	(15/37)	40.5	(15/33)	45.5	−44.4	NS
Not recorded	(1/15)	6.7	(4/45)	8.9	(1/36)	2.8	−58.3	NS
Total	(40/763)	5.2	(78/3165)	2.5	(50/2345)	2.1	−59.3	<0.0001

NS = nonsignificant.

Table 5 Effect on CF in Different Birth Weight Groups: 1995–2003

Birth weight	% Case fatality						% Change (1995–1996 to 2000–2003)	*p*
	1995–1996		1996–2000		2000–2003			
	(Deaths = 40, *n* = 763)		(Deaths = 78, *n* = 3165)		(Deaths = 50, *n* = 2345)			
≥2500 g	(1/417)	0.2	(14/1925)	0.7	(9/1514)	0.6	+147.9	NS
<2500 g	(36/320)	11.3	(59/1190)	5.0	(39/825)	4.7	−58.0	<0.0002
2000–2499 g	(9/246)	3.7	(18/943)	1.9	(8/658)	1.2	−66.8	<0.0300
1500–1999 g	(18/61)	29.5	(17/196)	8.7	(17/132)	12.9	−56.3	<0.0100
<1500 g	(9/13)	69.2	(24/51)	47.1	(14/35)	40.0	−42.2	NS
Weight not recorded	(3/26)	11.5	(5/50)	10.0	(2/6)	33.3	+188.9	NS
Total	(40/763)	5.2	(78/3165)	2.5	(50/2345)	2.1	−59.3	<0.0001

NS = nonsignificant.

Improved survival of preterm and LBW neonates was accompanied by a reduction in the incidence of comorbidities (Figures 2 and 3). In the LBW neonates, the incidence of sepsis, asphyxia and hypothermia decreased significantly. The incidence of feeding problems decreased by a smaller margin and was not significant. In the preterm neonates, the incidence of all four comorbidities decreased by almost half.

Effect of supportive care and of supportive care + treatment with antibiotics on CF in preterm-LBW neonates without sepsis and with sepsis is shown in Figure 4a. Similarly, the effect on CF in IUGR neonates is shown in Figure 4b. Among preterm-LBW neonates without sepsis, supportive care alone resulted in a significant reduction in CF. By contrast, supportive care alone did not result in a significant reduction in CF among preterm-LBW neonates with sepsis. In this group, CF was significantly reduced, from 61 to 13%, in those who received treatment with antibiotics + supportive care. Similar pattern was observed for the LBW-IUGR neonates as well.

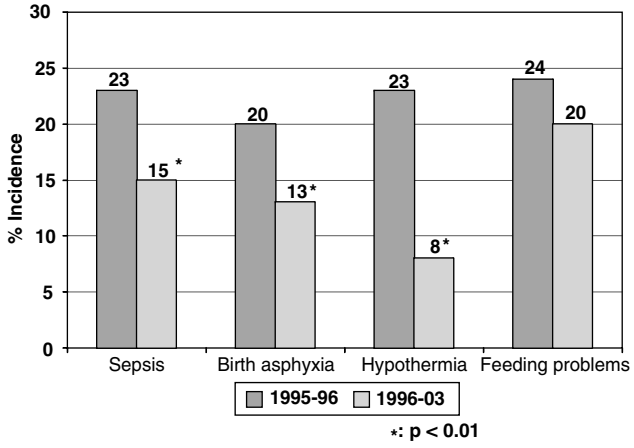

Figure 2. Effect on the incidence of comorbidities in low birth weight neonates: 1995 to 1996 vs 1996 to 2003.

As shown in Figure 1, different groups received different care in different years. The effect on CF of only supportive care, and of

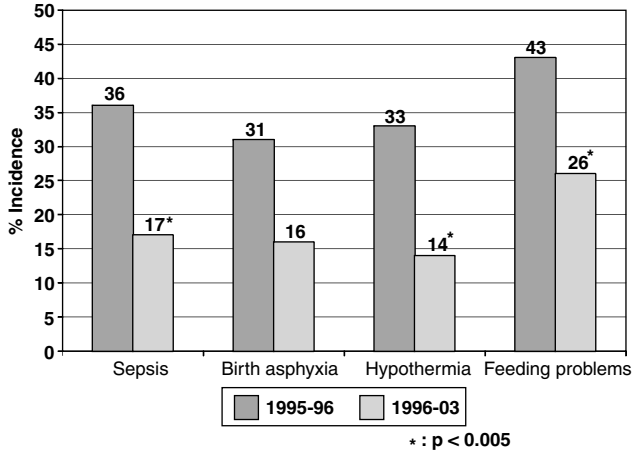

Figure 3. Effect on the incidence of comorbidities in preterm neonates 1995 to 1996 vs 1996–2003.

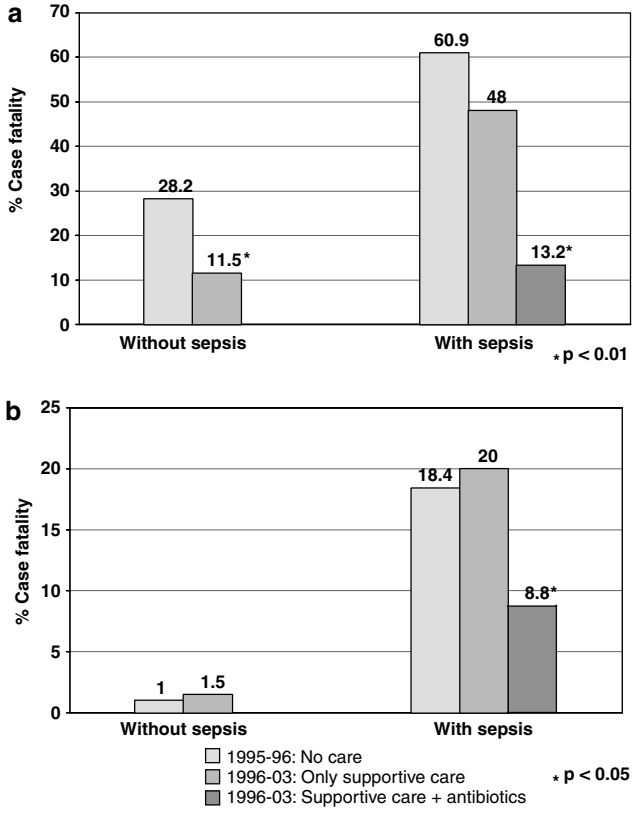

Figure 4. Effect of supportive care and treatment with antibiotics on CF among the low birth weight neonates: (1995 to 2003). (**a**) Preterm, low birth weight neonates and (**b**) full term, low birth weight (IUGR) neonates.

supportive care plus antibiotics, is presented separately for the preterm-LBW and the IUGR-LBW neonates in Table 6. Based on the absolute reduction in %CF, we have also disaggregated the effect of antibiotic therapy from the effect of supportive care. It is estimated that supportive care to all preterm-LBW neonates prevented total 55 deaths, accounting for 75% of the reduction in mortality; and the treatment with antibiotics contributed 25% of the total reduction. However, in the IUGR-LBW neonates, supportive care did not contribute to the reduction, and all prevented deaths (17) were attributed to the effect of treatment with antibiotics in IUGR neonates with sepsis.

The mean weight gain in LBW neonates during the neonatal period (1 to 28 days) did not show improvement; it was 566 g in 1995 to 1996, and 549 g during the intervention years (1996 to 2003). In preterm neonates, these values were 436 and 475 g, respectively.

DISCUSSION

In the 7 years of interventions in the field trial in rural Gadchiroli, 5510 newborns were managed at home, including 2015 LBW and 533 preterm neonates. With a resident VHW in each village, it was feasible to assess the neonates at birth and to identify LBW or preterm neonates and manage them at home with high coverage and quality. We observed no change in the incidence of preterm births and a modest (16%) but significant reduction in the incidence of LBW, mostly IUGR. On the other hand, the home-based management reduced the CF by nearly 60% for LBW and by nearly 70% for preterm neonates. Thus, the majority of the LBW or preterm neonates born in rural Gadchiroli could be effectively managed at home. A small proportion would still need referral.

Based on the preintervention data, we proposed a hypothesis that if the incidence of LBW/preterm could not be prevented, survival could still be improved by prevention/management of comorbidities, especially infection, in the LBW/preterm neonates.[8] The results of this study support this proposition. This is in line with the principles of managing LBW/preterm neonates in hospital. The essential approach is to prolong survival by preventing comorbidities and ensuring initiation of respiration at birth as well as feeding, warmth and protection from infection. We have applied the same principles in the home setting by training a VHW and mothers, with highly promising results.

Three factors explained the reduction in CF. First, there was a substantial decline in the incidence of comorbidities such as sepsis, asphyxia, hypothermia and feeding problems. Second, treatment with antibiotics in suspected sepsis contributed all of the observed decline in CF in the IUGR-LBW neonates, while in the preterm-LBW neonates, antibiotics therapy for the suspected sepsis contributed 25%, and third, the supportive care contributed 75% of the observed reduction in deaths in preterm LBW neonates. Overall, supportive care (home visiting, breastfeeding, thermal care) averted 55 deaths and treatment with antibiotics averted 35 deaths in LBW neonates.

This is a before–after comparison between the preintervention and the intervention years without an untreated control group. It would be unethical to detect LBW/preterm neonates in the control area and do nothing for them. However, we monitored the NMR

Table 6 CF in LBW Neonates: Effect of Supportive Care and Treatment with Antibiotics

Group	Year	Intervention	Neonates	Mean gestation (days)	*p*	Deaths	% CF	*p*	Absolute reduction in % CF*	Deaths prevented in 1996–2003†
(1) *Preterm, LBW*										
Without sepsis	1995–1996	No care	39	244	NS	11	28.2	<0.01*	—	—
Without sepsis	1996–2003	Only supportive care	270	243		31	11.5		16.7	45
With sepsis	1995–1996	No care	23	245	NS	14	60.9	NS	—	—
With sepsis	1996–2003	Only supportive care	25	240	NS	12	48.0	<0.005‡	12.9	3
With sepsis	1996–2003	Antibiotics+supportive care	53	244		7	13.2		47.7	25
Total	—	—	—			—	—	—	—	73
Net effect of treatment with antibiotics, viz: reduction in CF = 47.7−12.9 = 34.8 percentage points Deaths prevented by treatment with antibiotics = 53 × 34.8% = 18 Deaths prevented by supportive care in preterm-LBW neonates with sepsis = (25−18) = 7 Deaths prevented by only supportive care = 45+3+7 = 55 Percent contribution of supportive care to total number of prevented deaths (55/73) = 75% (95% CI = 65–85%)) Percent contribution of antibiotics to total number of prevented deaths (18/73) = 25% (95% CI = 15–35%)										
(2) *Full term, LBW (IUGR)*										
Without sepsis	1995–1996	No care	204	278	NS	2	1.0	NS	—	—
Without sepsis	1996–2003	Only supportive care	1409	278		21	1.5		−0.5	0§
With sepsis	1995–1996	No care	49	275	NS	9	18.4	NS	—	—
With sepsis	1996–2003	Only supportive care	45	277	NS	9	20.0	<0.05‡	−1.6	0§
With sepsis	1996–2003	Antibiotic+supportive care	181	275		16	8.8		9.6	17
Total	—	—	—			—	—	—	—	17
Deaths prevented by treatment with antibiotic = 17 Deaths prevented by supportive care = 0 Percent contribution of antibiotics to total number of prevented deaths = 17/17 = 100%										

CF = Case fatality; NS = nonsignificant.
*Compared to no care.
†Number of neonates in 1996–2003 × absolute reduction in % CF.
‡Difference in CF: with antibiotics vs without antibiotics.
§Assuming that supportive care cannot increase deaths.

and the IMR in the control area. As reported elsewhere, the NMR and IMR in the control area remained unchanged during the years of interventions.[16] As LBW and prematurity are the most important determinants of the NMR and the IMR, we can assume that the incidence and mortality due to LBW/preterm was unchanged in the control area and, hence, the observed changes in mortality in the intervention area can be attributed to the HBNC interventions.

Was the estimated gestation period correct? The period of gestation was estimated by VHWs on the basis of history given by pregnant women. The estimated mean duration of gestation remained consistent (276 days) during the different years (not presented). The mean birth weight progressively increased with the increase in the period of gestation (results: text). Moreover, a pronounced effect of the degree of prematurity was seen on CF (Table 4). These facts indirectly validate the estimated period of gestation. The early recording (usually in the 4th month of pregnancy) of the date of last menstruation by the VHWs who were women from the same village and culture may be one possible explanation of relatively reliable estimation of the period of gestation in our study.

No change occurred in the incidence of preterm birth. This is consistent with the conclusion drawn by the reviewers of various other intervention trials.[17] Generally, no effective intervention to prevent preterm birth is yet available.

The only preventive intervention against LBW was health education during pregnancy to overcome the voluntary ''eating

down'' prevalent in Gadchiroli[11] as well as in South Asia.[18] The mean birth weight increased by 112 g and the incidence of LBW declined by 16%, entirely due to reduction in the incidence of IUGR. Since no food supplements were given during this trial, the observed decline in the incidence of LBW suggests that nutrition education during pregnancy may have partly overcome the ''eating down'' practice. However, we did not measure the dietary intake in pregnancy and hence cannot test this.

Tables 2 and 3 show the feasibility of providing various HBNC interventions at a high coverage. This demonstrates the high acceptance by families and the potential of service delivery by VHWs. However, a few indicators, such as hand washing by mothers, referral to hospital or kangaroo mother care showed low coverage. The kangaroo mother care method has been reported to successfully reduce morbidities and CF in LBW/preterm neonates.[1,14] However, a recent review concluded that the quality of studies was unsatisfactory, and there is no conclusive evidence to recommend it.[19] Moreover, it has so far been used only in hospitals. We did not find good acceptance in our population (Table 3). A community-based trial in Bangladesh is currently underway (N. Sloan, personal communication).

In all, 2.8% LBW/preterm neonates (62/2199) received referral/hospital care (Table 2). CF in these 62 neonates was 22.6%.

Comparison with Other Experiences

In our study, the main change occurred in CF, which decreased by nearly 60 to 70%. It occurred in all birth weight or gestational strata, although by varied margins (Tables 4 and 5). How do these results compare with experiences elsewhere?

In an earlier field trial of detection and management of high-risk neonates in villages near Pune, India, LBW or preterm neonates were managed by better care at home and by referral.[20] Although the authors do not present separate data on the CF in the neonates managed at home, the CF in the LBW neonates (<2500 g) during the intervention period was reported to be 16% and in preterm neonates (<37 weeks) to be 35%. In comparison, CF in the Gadchiroli trial was much lower, that is, 5% for LBW and 10% for preterm. These differences were probably due to the treatment of infections by VHWs and relatively well-developed methods of health education and home-based management in the Gadchiroli trial.

In a feasibility trial conducted in rural north India nearly two decades ago, the LBW infants having suspected pneumonia were treated with oral penicillin. The CF in the intervention area was reported to be 8.7 vs 24.6% in the control area, and a 20% reduction in infant mortality rate was recorded. However, the study group included infants up to the age of 1 year, and the difference in the study and the control area was not significant.[21]

Comparison with the outcome of neonatal care in hospitals is difficult. Hospitalized neonates are likely to be selectively sicker. However, neonates born by hospital deliveries are less likely to be a selected population. A national database from 17 hospitals in India reports on nearly 50,000 hospital born neonates in the year 2000, among whom the NMR was 30 per 1000 live births and 33% of neonates were LBW,[22] very similar to the proportions among the neonates in Gadchiroli trial during intervention. The reported CF in different birth weight strata was also comparable (Table 7).

Although the effectiveness of the HBNC package in Gadchiroli in reducing the CF is satisfactory, nonetheless, a selected high-risk neonates had a high case fatality and needed hospitalization. These were:

1. <33 weeks gestation (CF 45.5%).
2. <1500 g birth weight (CF 40%).
3. LBW/preterm neonates whose feeding or body temperature could not be maintained at home.
4. LBW/preterm with sepsis who did not respond to treatment with antibiotics.

Similarly, although CF declined, the mean weight gain during days 1 to 28 did not substantially increase in either LBW neonates (566 vs 549 g) or preterm neonates (436 vs 475 g). These findings suggest the need for better strategies to feed preterm and LBW neonates.

Further research on home-based management of LBW/preterm neonates should focus on the application of the kangaroo mother care method in home settings, improved techniques of feeding in homes and developing a model of first-referral-level neonatal care for managing neonates who cannot be managed by HBNC. Apart

Table 7 Case Fatality in LBW Neonates in Hospitals in India and in Gadchiroli Trial

	National database (year 2000)*		Gadchiroli trial (2000–2003)	
Birth weight (g)	*n*	CF (%)	*n*	CF (%)
<1500	1,832	40.8	35	40.0
1500–1999	3,662	7.5	132	12.9
2000–2499	10,899	2.0	658	1.2

*National Neonatology Forum of India: National Neonatal Perinatal Database.[22]

from ensuring their survival, their weight gain in neonatal period needs to be improved so that they enter into the postneonatal period with less risk of death.

SIGNIFICANCE

The LBW and preterm births are associated with most of the mortality and a major proportion of morbidity in the neonatal period, and the importance of their prevention is undisputed. However, as long as we do not have effective methods of primary prevention, then secondary prevention, that is, case management and to increase the survival, is the practical option. The overwhelming effect of supportive care and treatment with antibiotics on mortality and morbidities observed in this trial suggests that the current situation of lack of care at home for needy neonates must change.

The significance of the results of this study is underscored by the fact that globally nearly 20 million LBW neonates are born each year, and that hospital-based care is not available to most of them. The cost of hospital-based care for LBW or preterm neonates is prohibitively high. In South Asia, where nearly one-third of neonates born are LBW, such a large load — nearly 11 million LBW neonates — can be possibly managed only by home-based care. We report the time inputs and cost required for providing HBNC elsewhere.[23]

This paper reports the efficacy of the HBNC approach in 39 villages. However, the major challenge is to provide such care on larger scale, as a part of the regular health services. Methods for scaling need to be developed, and effectiveness of HBNC in the health services setting need to be tested. We discuss this challenge in more detail elsewhere.[23]

IUGR-LBW babies are usually born in families who are poor and marginalized. Access to hospital is particularly difficult for these families. Thus, the LBW neonates represent probably the most disadvantaged and vulnerable group even within underdeveloped countries. The approach of home-based management can be a major step toward equity.

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