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Original Research Article

Outcomes in neonates with respiratory distress syndrome using SAANS NIV

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ABSTRACT

Background: In low-and-middle income countries (LMICs), neonatal mortality is still unacceptably high compared to developed nations. Respiratory distress syndrome (RDS) is one of the major contributors to high mortality rates in this population. This study was conducted to analyze the effects of Saans non-invasive ventilation (NIV), an infrastructure-independent continuous positive airway pressure (CPAP) and resuscitation device, on neonatal mortality and cost compared to current practices.
Methods: This single-center, prospective, observational analytical study was to determine the efficacy of Saans NIV in delivering CPAP and resuscitation therapy to neonates diagnosed with RDS.
Results: An 82% success rate was recorded while using Saans NIV for CPAP and resuscitation therapy in this study, which was far superior to the global average. This also means that 82% of the patients included in this study avoided invasive mechanical ventilation. After a cost analysis, we concluded that invasive mechanical ventilation would cost $3478 USD for treatment vs. just $155 USD for patients treated with traditional CPAP therapy.
Conclusions: Infrastructure-independent devices such as Saans NIV are game-changers in LMICs. Saans NIV makes CPAP and safe resuscitation therapy available in resource-constrained settings and during transport. This study showcases that Saans NIV can significantly reduce the need for invasive mechanical ventilation and the costs associated with treating neonates.

Keywords: RDS, CPAP, Neonatal mortality, LMICs

INTRODUCTION

Neonatal mortality (death in the first 28 days after birth) continues to be unacceptably high in large parts of the world, mainly the LMICs in Asia and Africa.[1] While the global neonatal mortality rate has almost halved from 1990 to 2016, most of these gains have been in middle-and-high-income countries.[2] LMICs have made much less progress in reducing neonatal mortality due to a lack of healthcare resources.

Ethiopia is a low-income country that has made significant progress in deploying advanced technologies to combat child mortality. From 1990 to 2013, Ethiopia reduced neonatal mortality from 50 to 28 deaths per 1000 live births. While this is commendable, this still falls well short of the UN's sustainable development goal of 12 deaths per 1000 live births.[3] One of the leading causes of neonatal morbidity and mortality is RDS leading to respiratory compromise (RC) which is typically seen as a consequence of prematurity. RDS is the leading cause of neonatal morbidity and mortality in Ethiopia, besides leading to high neonatal care costs, which are unaffordable by the typical Ethiopian family.

In countries with high neonatal mortality, an effective way to provide respiratory support to neonates with RDS

would significantly reduce neonatal morbidity and mortality. Presently, invasive mechanical ventilation (IMV) is the only option provided to neonates diagnosed with RDS and RC in these countries. Limitations in trained professionals and appropriate infrastructure results in unacceptably high mortality rates in low-resource countries. Regrettably, mortality rates in artificially ventilated neonates are reported as high as 46% by Sangeeta et al 70.6% by Hossain et al and 74% by Mathur et al in Gujarat, Bangladesh, and India, respectively.[4-6] An alternative to IMV is CPAP. CPAP is an easy-to-use, simple, and non-invasive form of respiratory support that requires less advanced technical expertise compared to IMV. Therefore, CPAP therapy is strongly recommended by the world health organization for the treatment of neonates with RDS in low-resource countries.[7] Unfortunately, non-invasive ventilation machines are scarce within the public sector in low-resource settings due to cost and lack of supporting infrastructure.[8] Currently, there are two neonatal breathing support systems that are used in low-resource settings. The first is the Bubble CPAP, which is used to provide long-term breathing support. Bubble CPAPs require electricity and compressed gasses and are limited to stationary use. Second is a manual resuscitator used with unblended oxygen gas for acute asphyxia and short-term transport.

To tackle these issues faced by low-resource settings, an affordable, easy-to-use, and infrastructure-independent CPAP and resuscitator combination device 'Saans NIV' was developed by InnAccel technologies private limited. Saans NIV is operable in resource-constrained settings as it delivers CPAP therapy in multiple operating modes, including battery, compressed gas, and a unique manual mode if electricity or an oxygen source is unavailable. Therefore, this device is not constrained by the absence of electricity. Saans NIV is also portable and can be used during transport. Due to its affordability, alignment with resource-constrained settings, and ease of use, Saans NIV has the potential to reduce neonatal morbidity and mortality in Ethiopia and any part of the world where resources are scarce.

Aim

This single-center, prospective, observational analytical study was to determine the efficacy of Saans NIV in delivering CPAP and resuscitation therapy to neonates diagnosed with RDS.

Settings

This single-center study was conducted at Hallelujah general hospital in Ethiopia from October 2021 to January 2022.

METHODS

Saans NIV is a portable and infrastructure-independent neonatal CPAP for long-term breathing support. It can provide resuscitation by delivering appropriately blended oxygen efficiently to neonates without causing damage to their fragile lungs, which is an issue faced when using a basic bag valve mask. Saans NIV is equipped with an integrated air-oxygen blender and a built-in compressor that allows this device to function without a compressed gas source. The air-oxygen blender can deliver FiO_2 based on a blending chart that is provided along with the device. This device is also portable, meaning that it can work with or without a source of electricity due to its backup battery or manual mode.

Training was provided to all nurses, doctors, and other staff involved in this study to ensure that the device was correctly used, and accurate data was collected. Saans NIV devices, along with consumables, were provided to this hospital. Retrospective baseline data was collected for three months prior to the deployment of Saans NIV. The following data were collected: the number of neonates diagnosed with RDS, the number of neonates referred to a more equipped facility and the number of neonates who required invasive mechanical ventilation. Mortality data was not available for babies referred out for IMV.

All neonates diagnosed with RDS prescribed CPAP therapy by a physician were included in this study. Neonates transferred from other facilities for a higher level of care were also included. Neonates diagnosed with chromosomal abnormalities and congenital deformities were excluded from this study. A positive outcome in this study was considered discharge after successful CPAP therapy. A negative outcome was defined as a shift to IMV or death.

Sample size

Sample size was determined by the retrospective data that was collected from this facility. A sample size of 39 was chosen for fair comparison against the retrospective data of 38 patients.

Statistical analysis

Statistical analysis was not completed due to the small sample size of this study.

Ethical approval

Approval for this study was taken from an independent ethics committee.

RESULTS

Retrospective baseline data

In the three months that retrospective baseline data was collected, 38 neonates were diagnosed with RDS. Out of these 38 neonates (Figure 1), n=32 (84.2%) were transferred to other facilities for IMV due to the lack of

equipment, and only n=6, (15.8%) were successfully treated and discharged from Hallelujah general hospital. Due to the lack of resources, data on these neonates and their treatment after they left Hallelujah general hospital were not collected. The transfer of these patients was a major financial loss for the hospital and these neonates faced unsafe conditions during transport due to only a bag valve mask being available for respiratory support.

Prospective data

During the four months, this study was conducted, 39 neonates were prescribed CPAP and resuscitation therapy. The clinical conditions of participants are given in Table 1. Of the 39 neonates, 32 were treated using CPAP therapy and the remaining seven were treated using the resuscitation mode. Saans NIV was used for a total of 1243.8 hours.

Table 1: Clinical conditions.

Clinical condition	Number of neonates, N (%)
Respiratory distress	31 (79.49)
Cardiac arrest	5 (12.82)
EONS/ septic shock	3 (7.69)

Out of the 39 neonates that were treated using Saans NIV (Figure 2), n=32 (82%) was successfully treated and discharged home, n=3 (7.7%) was referred for invasive mechanical ventilation, n=1 (2.6%) was transferred using Saans to a higher level of care facility, and n=3 (7.7%) deaths occurred. None of these three deaths were caused by the device.

This data shows that Saans NIV is a viable option in low-resource settings to provide respiratory support to neonates. This facility provided care to 39 neonates due to the implementation of Saans NIV with an 82% success with CPAP therapy. The risk of adverse events during transport was also reduced due to Saans NIV's ability to provide therapy during transport because of its battery-powered mode. This was highlighted by the fact that one patient was stabilized using Saans NIV and transported to another facility for a higher level of care. 82% of the n=39 was counted as a positive outcome in this study because these neonates did not pass away, need IMV and were able to wean off of CPAP and be sent home.

The 32 patients treated with Saans NIV CPAP therapy spent approximately two days on average on the device for respiratory support. This is consistent with current data that indicates that most neonates with mild RDS recover within a few days.[9] As a result of being able to be treated at Hallelujah general hospital on Saans NIV, accrued costs were only between 2000-4000 Ethiopian Birr ($39-78 USD) per day of treatment vs. 10000-15000 Birr ($194-290 USD) in costs which would have been incurred per day if the patient was referred and transferred to a different facility for IMV.

From the results of this study, we find that Saans NIV is an effective device that can successfully provide CPAP therapy and resuscitation to neonates in low-resource settings and offers this at a lower cost compared to IMV with better outcomes.

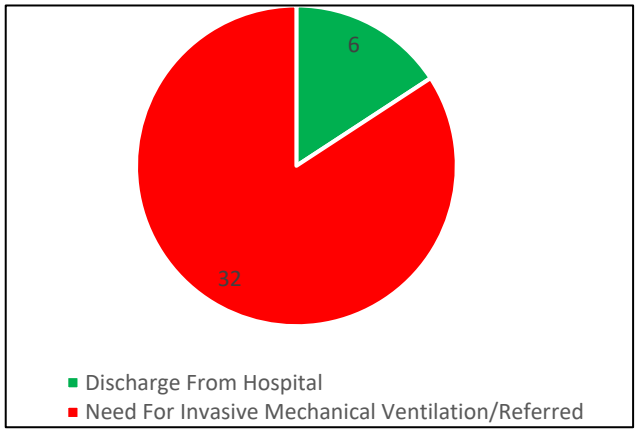

Figure 1: Outcomes prior to Saans outcome.

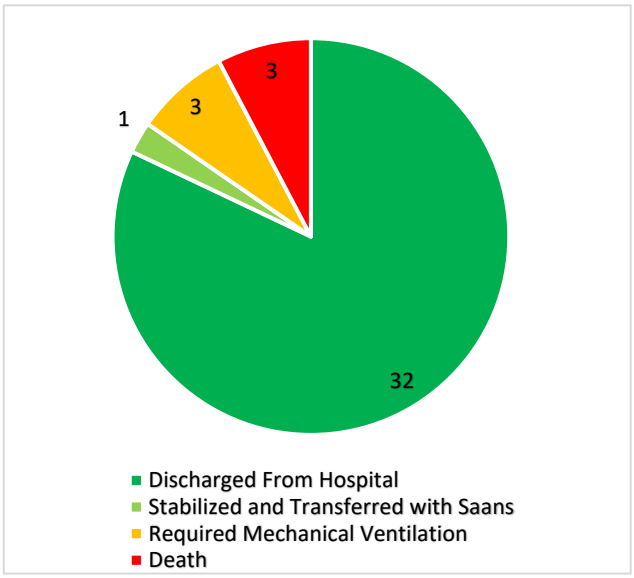

Figure 2: Saans outcomes.

DISCUSSION

In 2020, an estimated 2.4 million neonates perished during the most vulnerable period of their life. More than one-third of these deaths were due to complications such as RDS. In developed countries, RDS is managed effectively due to the availability of antenatal corticosteroid therapy, mechanical ventilators, and surfactant replacement therapy. Unfortunately, LMICs such as Ethiopia lack the resources to acquire enough of these advanced forms of treatment. In such settings, CPAP therapy is an effective treatment.[14]

The first issue that we can tackle using a device such as Saans NIV, which is a novel breathing support system that was evaluated, is significantly reduce the number of

neonates that require IMV. It is estimated that the odds of dying in a LMIC like Ethiopia is 12.29 times greater for mechanically ventilated patients than those who receive CPAP therpay.[10] Various studies have also indicated that mortality rates in developing countries within this population are between 40-60%.[10,11] Initiating CPAP therapy as early as possible will ensure that neonates in these low-resource areas are given a fighting chance.

Next, previous studies have shown that CPAP therapy has effectively reduced the risk of mortality in infants by 48% and the need for surfactant and mechanical ventilation by about 50%.[12,13] CPAP therapy is the superior option for treating neonates with RDS compared to IMV. Saans NIV can provide CPAP therapy effectively in resource-constrained settings, and the ease of use of this device allows it to perform exceptionally well in areas where training and expertise are lacking.

Thirdly, IMV is a costly affair compared to traditional CPAP therapy. Neonates who were invasively ventilated in a study on the duration of mechanical ventilation in neonates spent an average of 12 days ventilated with a case mortality rate of 38%.[14] We calculated that per neonate on IMV, it cost $3478 USD for treatment vs. just $155 USD for patients treated with traditional CPAP therapy in our trial. This estimate is based on information gathered from Hallelujah General Hospital. Saans NIV is a device that costs less than $3,000 USD. This cost can be recouped by preventing just one neonate from being placed on IMV, reducing the mortality rate significantly.

Finally, this study recorded an 82% success rate while using Saans NIV for CPAP therapy, which is far superior to the global average, where only about 50% of neonates avoid needing to be invasively intubated and ventilated. This system's pilot displays the positive effects of enabling hospitals in LMICs by tailoring innovative designs to ensure that every neonate is given a chance to thrive.

Limitations

A limitation of this study is the sample size. This sample size did not allow us to complete statistical analysis of these results.

CONCLUSION

Saans NIV is an outstanding device for LMICs like Ethiopia due to its infrastructure-independent design. This device can provide lifesaving respiratory support to neonates in extremely low-resource healthcare settings. It is also a cost-effective device because it can save hospitals and patients who are already struggling to get by.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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