Scholars Journal of Applied Medical Sciences
Abbreviated Key Title: Sch J App Med Sci
ISSN 2347-954X (Print) | ISSN 2320-6691 (Online)
Journal homepage: https://saspublishers.com

OPEN ACCESS

Pediatrics

Exchange Transfusion in Neonatal Sepsis- An Old Wine in New Bottle

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DOI: 10.36347/sjams.2021.v09i06.006 | **Received:** 03.02.2021 | **Accepted:** 27.05.2021 | **Published:** 03.06.2021

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Abstract **Original Research Article**

Neonatal Sepsis, second major cause of mortality, is killing more than one million neonates annually worldwide [1]. Globally, of three million annual neonatal sepsis cases India has the highest incidence of clinical sepsis (17,000/ 1, 00,000 live births) [2]. In the 1980s and 90s, exchange transfusion (ET) was reported by some authors to be effective in the treatment of neonatal sepsis and septic shock [3]. The main aim of this study was to assess the efficacy of exchange transfusion in neonatal sepsis as compared to standard therapy. Neonates with septic shock (Sclerema) admitted to our NICU from dec 2017 to dec 2018 were included in the study. 43 neonates who received ETs were compared with 43 neonates who received of standard care therapy. The mortality rate was 27.9% in the ET group and 30.1% in the ScT group statistically insignificant. The duration of hospital stay in exchange transfusion babies was less(14.9 days) as compared to control group(22.7days) which was statistically significant($p<0.05$). In the era of increasing antibiotic resistance, the need of hour is to find alternative measures in sepsis. Exchange transfusion can be one of the prime modality in treatment of severe neonatal sepsis, which is one of the major cause of deaths worldwide. Exchange transfusion being cheaper as compared to other modalities of treatment (eg; IVIG) needs further research on use and long term complications in neonatal sepsis.

Keywords: Neonatal sepsis, sclerema, exchange transfusion.

INTRODUCTION

Septic shock, is a major cause of death in the neonatal period with case fatality rate ranging between 25% to 65% in India [4]. According to NNPD, Incidence is 30 per 1000 live births [4]. Sepsis one of the commonest causes of neonatal mortality contributing to 19% of all neonatal deaths [5]. ET was proposed as an adjunctive therapy in neonates with severe sepsis in last decade but [5] Despite its potential benefits, clear evidence for its clinical efficacy is lacking, as most reports were anecdotal or conducted on small groups of neonates without comparative controls [6].

NNF of India has defined neonatal sepsis:

Probable (Clinical) Sepsis

- Clinical picture suggestive of septicemia +
- Existence of predisposing factors:
- Maternal fever or
- Foul smelling liquor or
- Prolonged rupture of membranes (>24 hrs) or
- Gastric polymorphs (>5 per high power field).

Positive septic screen

Two of the four parameters namely,

- TLC < 5000/mm,
- I:E ratio of >0.2,
- ANC < 1800/cumm,
- CRP >1mg/dl
- Micro ESR > 10 mm-first hour.
- Radiological evidence of pneumonia.

Culture Positive Sepsis

Clinical picture suggestive of septicemia, pneumonia or meningitis

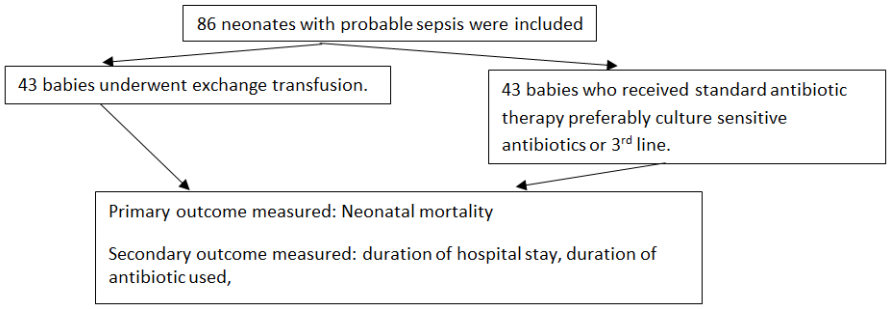
- Isolation of pathogens from blood or CSF or urine or abscess
- Pathological evidence of sepsis on autopsy.

In our study, clinical picture (esp Sclerema) and TLC, ANC and CRP for defining neonates with sepsis.

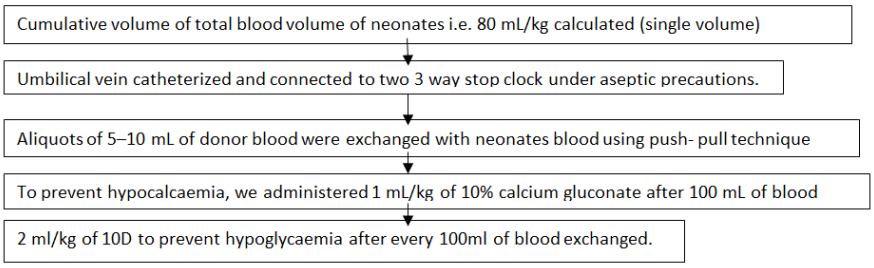
AIMS OF STUDY

To assess the efficacy of exchange transfusion in neonatal sepsis as compared to standard antibiotic therapy.

MATERIALS & METHODS



Procedure



The procedure completed within 90–150 min. Always whole blood was used which was compatible with babys ABO group and mothers Rh. The anticoagulant used in donor blood was CPD and was negative for HbsAg, HCV, MP, VDRL and HIV.

Pre and post exchange counts, CRP and culture was done. Vitals monitored throughout and after the procedure.

The response to treatment was evaluated on the basis:

- Mortality {as compared to study group}
- Clinical improvement
- Improvement in counts and CRP.
- Duration of stay in hospital
- Duration of antibiotic usage.

These parameters were compared with cross matched control groups for the study. Statistical analysis was done by applying Fischer's Exact Test, $p<0.005$ was taken statistically significant.

RESULTS

- Of the 86 babies who were taken for study all neonates required circulatory and respiratory support in the form of inotropes and CPAP or mechanical ventilation or oxygen respectively.
- The study group had 28% of preterm and control 21%. The clinical profile in study and control group was comparable with regards to age, sex, gestational age and duration of hospital stay (Refer Table – 1).
- PMA of all of the exchange transfusions was from 5^{th} to 12^{th} day of life.
- The commonest microorganism in both the groups was Enterobacteriae followed by Klebsiella.
- The overall mortality between both the groups was similar with no statistical significance.
- The duration of hospital stay in exchange transfusion babies was less(14.9 days) as compared to control group(22.7days) which was statistically significant($p<0.005$).

Table-1: Comparison of clinical parameters between study and control group.

Parameters	Control group	Study group
Male: Female	1.6:1	1.6:1
Mean gestational age	33.6 wks	33.1 wks
Preterm	12(28%)	9(21%)
Mean duration of hospital stay (Days)	22.6	14.9
Mean duration of antibiotic usage(Days)*	21	9

Note: Mean duration of antibiotic use was accounted from the time of development of signs and sepsis in both the groups.

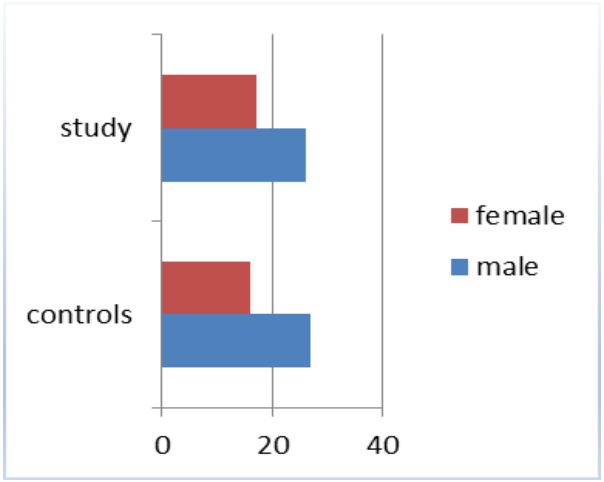


Fig-1 Distribution of male: female in study and control group

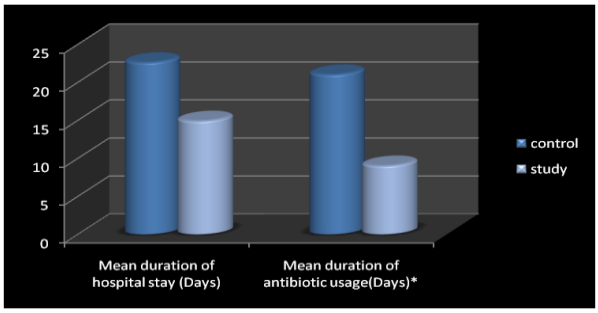


Fig-2: Graph showing difference in the mean duration of stay at hospital and antibiotic use between control and study group

Inference:

- The ratio of male: female was comparable.
- There was significant reduction in the mean duration of hospital stay and antibiotic use in the babies who underwent exchange transfusion.

Table-2: Bacterial isolates in controls and study groups

Organisms	Control group		Study group	
	Cases	Mortality (%)	Cases	Mortality (%)
Enterobacter	10	2(20%)	15	05(33.3%)
Staph. aureus	07	04(57.1%)	05	01(20.0%)
Klebsiella	09	05(55.5%)	11	4(36.36%)
Total*	26	14(53.8%)	36	10(27.8%)

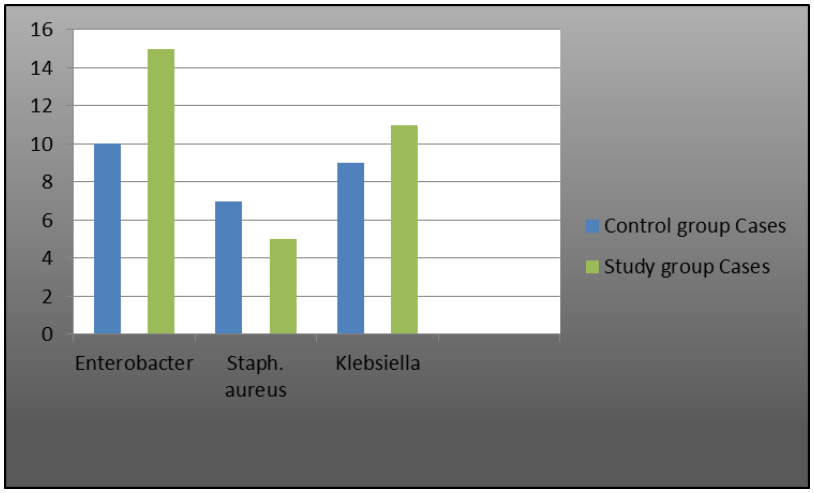


Fig-3: Growth of bacteria in study and control groups.

Inference:

Both the groups grew enterobacter followed by klebsiella. Mortality in both the groups was highest with culture growth of Klebsiella.

Table –3: Outcome in study and control group based on culture positivity

Culture	Study group		Control group	
	Cases	Mortality (%)	Cases	Mortality (%)
Positive	36	10(27.77%)	26	7(26.9%)
Sterile	7	02(28.57%)	17	05(29.4%)
Total	43	12(27.9%)	43	13(30.2%)

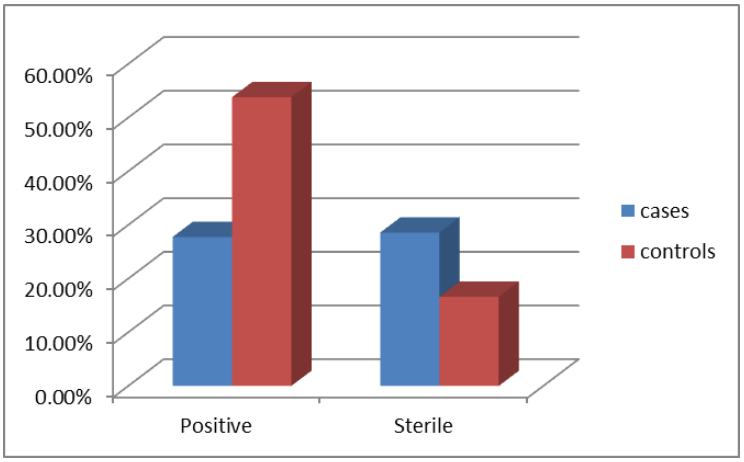


Fig-4: Mortality based on culture

Inference:

- Mortality in both the groups was almost similar.
- Mortality in study group was mostly of those babies whose culture was positive.

Table-4: Gestational age wise comparison of mortality in two groups

Gestational age	**Control group**		**Study group**	
Gestational age	Cases	Mortality (%)	Cases	Mortality (%)
Preterm	12	04(9.33%)	09	02(4.67
Term	31	9(20.9%)	28	08(18.6
Posterm				0602(4.67%)
Total	43	13(30.%)		4312(27.90)

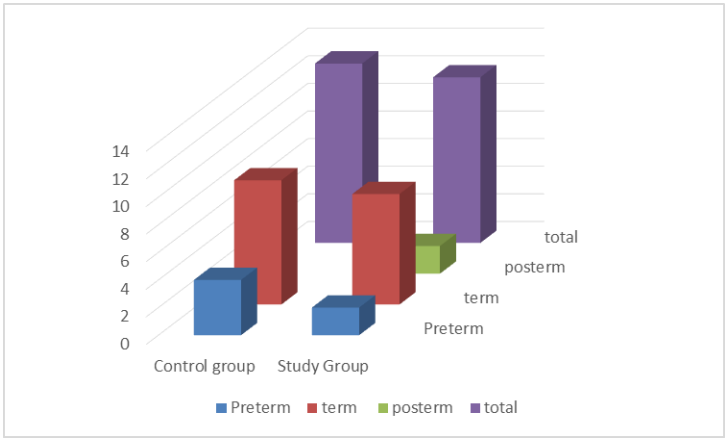


Fig-5: Mortality on the basis of gestational age group.

Inference:

There was no significant difference in the mortality of both the groups.

Table –4: Comparison of average length of stay in hospital

Gestational age	Control group No. of days	Study group
Pretrem	29.5	22.7
Term	17.4	10.7

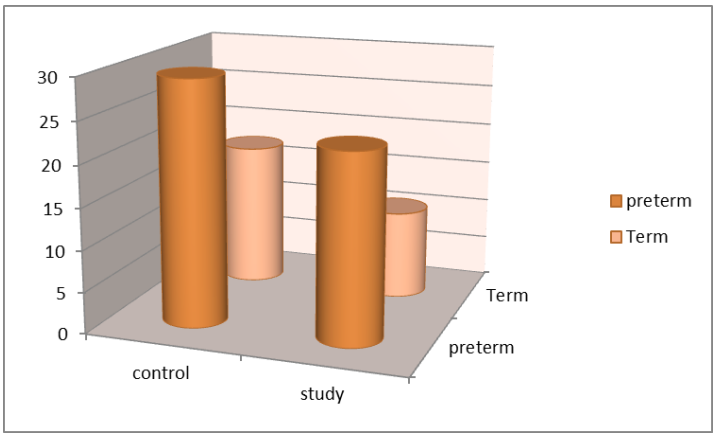


Fig-6 Comparison of duration of stay at hospital between study and control groups

Inference:

There was significant reduction in the duration of stay of hospital which was statistically significant. ($p<0.005$)

DISCUSSION

To date, only three randomized controlled trials have been published which are suggestive that exchange transfusion reduces mortality in neonatal sepsis.

Table-7: Comparison among different studies mortality between cases (underwent exchange transfusion) and controls (received standard antibiotic therapy)

Mortality	Mathur et al. [6] 1993	Sadana et al. [6] 1997	Aradhya et al. [6]	Our study
Case	35%	50%	25%	27.9%
Controls	70%	95%	46%	30.2%

Our study suggests that there is no significant in reduction in mortality in children with sepsis underwent exchange transfusion as the death rate in both the study groups was same without any statistical significance. There was significant reduction in duration of antibiotic use and the duration of stay in hospital in the study group who underwent exchange transfusion in our study.

The rationale for the use of ET using fresh, compatible cross matched whole adult blood [6] is

- Reduction of bacterial load and endotoxins, and circulating pro-inflammatory cytokines.
- To improve perfusion and tissue oxygenation.
- To correct the plasma coagulation system.
- To enhance immunological defense mechanisms (increase in circulating levels of C3, immunoglobulins, improvement in the opsonic activity against the pathogen, enhancement of neutrophil function) [3].
- To replenish the fresh compliment component, neutrophils, lymphocytes.
- To replenish fresh clotting factors.

In our study, the common complications encountered were

Table-8: Common complications that occurred during the procedure

Complications	No. of cases	% of cases
Hypocalcemia	6	13.9
Hypoglycemia	11	25.5

Drawbacks

- As the sample size is relatively small in this study, the result need to be substantiated by larger trial.
- Proper randomization of cases for comparison was not possible
- Long term follow up of the patients could not be done as patients were lost for follow up. Long term side effects of exchange transfusion could not be assessed.

CONCLUSION

In the era of increasing antibiotic resistance, the need of hour is to find alternative measures in sepsis. Exchange transfusion can be one the prime modality in treatment of severe neonatal sepsis, which is one of the major cause of deaths worldwide. Exchange transfusion being cheaper as compared to alternate modalities(eg IVIG) needs further research on use in neonatal sepsis.

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