

“The Management of Term Babies born after PROM using Little to No Antibiotics at PMGH”



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Introduction

- PROM - rupture of amniotic membranes ≥ 18 hrs prior to delivery
- In PNG, >12 hrs considered PROM
- PROM complicates approximately 8-10% of pregnancies at term
- **Risk factor** for neonatal sepsis particularly **early onset neonatal sepsis (EONS)**

- **Incidence** of neonatal sepsis in babies of women with PROM: **1-2.6%**
- **Antibiotics (ABX)** given to **mothers** with PROM **delays delivery & reduces infections** in mothers and their babies
- For **term well newborns**, management varies;
 - dependent on hospital protocols
 - clinician's experience and preference
 - based on observational studies - increase risk of sepsis with certain risk factors

- **In PNG** - ABX recommended to be given and stopped after 3 days if baby remains well

(Standard Treatment for Common Illnesses of Children in Papua New Guinea. A manual for nurses, community health workers, health extension officers and doctors. 10th edition. 2016)

- **A 2004 Cochrane review concluded:**
 - **Insufficient evidence** to support the use of **prophylactic** ABX in well, term newborns after PROM and other maternal risk factors for neonatal infection
 - More trials needed
- **Prophylactic use** of ABX in **well babies** may lead to **complications**

Aim

Determine if it was **safe and effective** to use a **simplified management approach** to asymptomatic babies born after PROM, designed to **reduce exposure to antibiotics**

Methodology

Study design & site

- A prospective, observational, non-randomised, intervention study at PMGH labour ward and post-natal ward
- August 2016 - May 2017



Study Participants

Inclusion Criteria

- Mothers had PROM > 12hrs
- No clinical signs of sepsis
- Term delivery (≥ 37 wks)
- Hospital delivery
- Good APGAR (≥ 7 @ 5mins)
- Birth weight ≥ 2 kg

Exclusion Criteria

- Mothers had PPROM (<37 wks)
- Not meeting inclusion criteria

Simplified Management Approach

Mothers who received intrapartum ABX
No ABX for babies

Mothers who received no intrapartum ABX
Stat ABX for babies
Amoxcil 30mg/kg & Gentamycin 5mg/kg

Screened @ 12-24hrs & 36-48 hrs for clinical signs of infection

No clinical signs of sepsis present

Discharged

Review earlier if baby sick

Review 6-8 days

No clinical signs of sepsis present

Discharged from study

Clinical signs of sepsis present

Clinical signs of sepsis present

- **Investigations-FBE, BC & cultures of other sites**
- **Antibiotics given**
- **±SCN admission**
- **D/C if all well**

Clinical features by WHO used to assess for sepsis

- **Reduced feeding**
- **Fever (Temp $\geq 37.5^{\circ}\text{C}$)**
- **Hypothermia (Temp ≤ 35.5)**
- **Severe chest indrawing**

- **Fast breathing (RR >60 /min)**
- **Convulsions**
- **Jaundice in first 24 hrs**
- **Jaundice at any age**

Clinical features for local sepsis also checked

- **Purulent eye discharge**
- **Skin pustules**
- **Purulent or erythema surrounding umbilical stump**

Primary Outcome

- Development of neonatal sepsis within 7 days
- Defined clinically or confirmed with cultures

Secondary Outcomes

- Admission to SCN or paediatric general ward with neonatal sepsis 8-28 days
- Any mortality

Data Collection

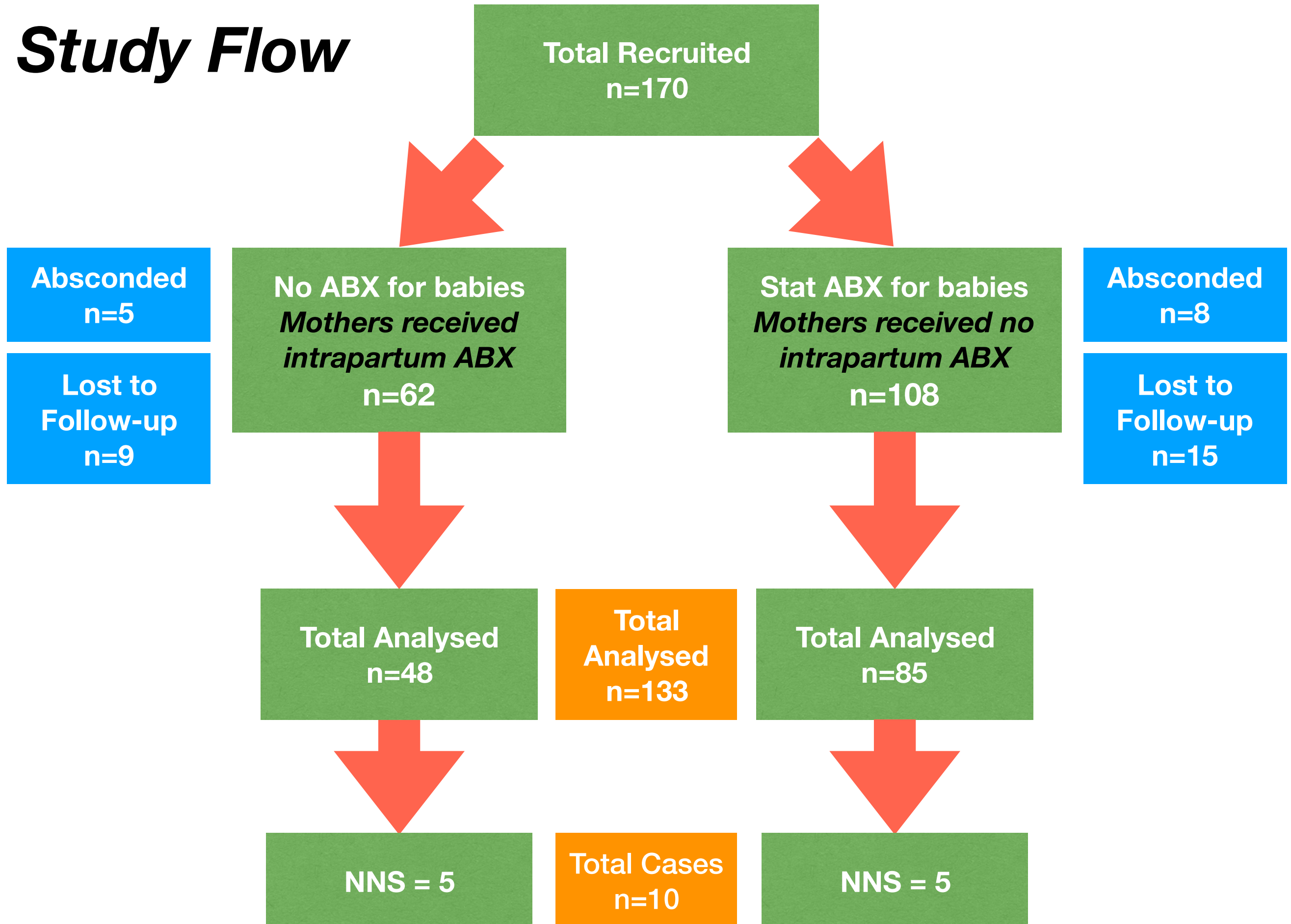
- Data collection form
- Maternal characteristics; Antenatal, intrapartum & delivery details
- Neonatal characteristics; Follow-up details; Ascertainment & documentation of neonatal sepsis

Data Analysis

- Excel spreadsheet, AcaStat statistical software version 2200 & Epi info stat calc

Results

Study Flow



Maternal characteristics

Variables	No. of cases n=133 [n(%); mean±SD]
<i>Basic Demographics</i>	
Age (years)	24.7 ± 4.4
Education Level	
Primary	36 (27.1)
Secondary	63 (47.4)
Tertiary	30 (22.6)
Uneducated	4 (3.0)
Smoker (Yes)	24 (18.1)
<i>Antenatal History</i>	
Booked (Yes)	129 (96.9)
RVI (Yes)	2 (1.5)
Syphillis (Yes)	5 (3.8)
Parity (Primigravida)	76 (57.6)
Previous history of PROM (Yes) (parity > 1; n=67)	15 (22.4)

Maternal characteristics

Variables	No. of cases n=133 [n(%); mean±SD]
<i>Intra-partum and Delivery</i>	
Gestational Age (weeks)	39 ± 1.4
Delivery mode	
NVD	100 (75.2)
C/Section	21 (15.8)
Instrumental	12 (9.0)
SRM (Yes)	105 (79)
Duration of PROM (hours) [mean (SD)]	24.9 ± 12.6
Labour	
Induced (Yes)	31 (23.3)
Augmented (Yes)	63 (47.4)
Duration of labour (hours)	20.1 ± 13.1
Intrapartum antibiotics (Yes)	48 (36.1)
Meconium staining of liquor (Yes)	20 (15)
Signs of chorioamnionitis (Yes)	6 (4.5)

Neonatal characteristics

Variables		No. of babies n=133 [n(%); mean±SD]
Birth weight (kg)		3.2 ± 0.49
Sex	Male	68 (51.1)
	Female	65 (48.9)
Apgars [mean (SD)]		
1 minute		8.6 ± 1.2
5 minutes		9.9 ± 0.5
Discharge time		
48 hrs		96 (71.2)
72 hrs		37 (27.8)
Review day		
6		15 (11.3)
7		87 (68.4)
8		13 (9.8)
9		7 (5.3)
10		3 (2.3)

Outcome measures

	Total	Group	
	No. of babies n=133 [n(%)]	No ABX n=48 [n(%)]	Stat ABX n=85 [n(%)]
Primary Outcome			
Sepsis (Yes)	10 (7.5)	5 (10)	5 (6)
Time when clinical sign of sepsis evident			
24 - 72 hrs	6 (4.5)	2 (4)	4 (5)
> 72 hrs - 7 days	4 (3.0)	3 (6)	1 (1)
Secondary Outcomes			
Sepsis developed 8-28 days	4 (3)	2 (4.2)	2 (2.4)
Neonatal mortality	0	0	0

- Clinical features of babies who developed NNS
 - ***5 isolated fever, 1 fever with umbilical redness (cord infection), 4 skin pustules (skin sepsis)***
- Blood culture positive in 2 out of 10 babies with sepsis
 - Moraxella species & CNSA (probable contaminant)
- Pus swab grew Staphylococcus aureus in 3 of the 4 babies with skin pustules
- 4 babies admitted to general paediatric ward between 8-28 days; 2 skin sepsis & 2 isolated fevers

Discussion

- **Overall rate of suspected or proven sepsis - 7.5%**
- Other studies: 2.4%, 4%, 17.6%
- Differences
 - Sample size
 - Population
 - Definition of PROM
 - Definition of sepsis
 - Intervention & antibiotics used
 - Population of mothers
 - Environmental context

- **119 of 133 babies (89.5%) received minimal to no exposure to antibiotics**
- Studies have shown
 - ABX in neonatal period an independent risk factor for wheezing during first year of life
 - ABX in first few weeks of life affects colonisation of the neonatal intestine - leads to removal of commensal flora

Limitations

- Small sample size
- No background sepsis rate with current management used at PMGH to compare with our study rate

Conclusion

- Acceptable sepsis rate (7.5%) in term babies born after PROM using the new simplified management approach with little to no antibiotics
- 89.5% of well babies received little to no antibiotics, avoiding possible complications associated with antibiotics therapy
- Study highlights need for structured clinical assessment of high risk babies before they are discharged home

Recommendation

We recommend little to no antibiotics as a safe and effective way of managing asymptomatic term babies born after PROM

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