Early Identification and Prevention of Postnatal Complications among the Postnatal Mothers by Using the ‘Postnatal Care Bundle’

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Authors’ contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: Postnatal period initiates immediately after the birth of a baby. The terms puerperium period is commonly used to refer to the first 6 weeks after delivery of baby. A postnatal care bundle used during this period and it will help to significantly improve patient outcomes.

Objective: To develop, test and pilot of Postnatal Care Bundle (PNCB) and to assess conventional postnatal care among the postnatal mothers and to evaluate the effectivity of Postnatal Care Bundle (PNCB) for early identification and prevention of postpartum complications among the postnatal mothers and to assess the satisfaction level of staff nurses after implementation of Postnatal Care Bundle and conventional postnatal care for early identification and prevention of postnatal complications among the postnatal mothers.

Methodology: The interventional analytical and true experimental research design approach will be used and the sample use for the postnatal mothers including the full term normal delivery, caesarean section will be and the random sampling use and sample size is 185 in each group i.e.

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control and experimental group. One group will be received conventional postnatal care and other group will be on postnatal care bundle. The outcome includes that postnatal care bundle help to early identification and prevention of postnatal complications among the postnatal mothers. 

**Conclusion:** PN CB will be effective in quality care of postnatal period.

**Keywords:** Care bundle; postnatal care bundles; postnatal mothers; postnatal complications and postnatal management.

1. **INTRODUCTION**

Postnatal period starts from after birth up to six weeks [1]. The World Health Organization (WHO) states that postnatal period is the crucial period as well as the most neglected phase for mothers and babies and mostly maternal and/or newborn deaths occur during this period [2].

The postpartum period can be divided into three different phases. The first also called as the initial or acute phase is last for 6-12 hours after delivery and subacute postnatal period which lasts 2-6 weeks. If this period last up to 6 months is called as delayed postpartum period. In subacute period, 87% to 94% of women report at least one health problems and long term health problems (persisting after the delayed postpartum period) are reported by 31% of women [3].

Worldwide, approximately every day 800 mother die due to pregnancy and its related causes. In 2013, around 289,000 mothers died during pregnancy and childbirth. Developing countries accounts 99% of all these maternal deaths which is from rural areas and poor communities [4,5].

Maternal mortality is the very common in developing country. The 80% mother deaths are the concealed [6,7]. Sixty percent of women deaths occur in the postpartum period [8]. Postpartum haemorrhage is the foremost cause of maternal morbidity and mortality at a worldwide scale [9-11].

As per WHO nearly five mothers die each hour in India due to problems developed during childbirth and main caused is heavy blood loss. Nearly 45,000 mothers die and causes of this is childbirth [12,13]. This works out to losing nearly five mothers every hour [14,15].

A care bundle is a set of interventions that used together; it will be significantly improve patient outcomes. Multidisciplinary health professional teams used to care to the patients and nursing intervention supported by evidence-based research and defiantly it will helps outcome of patient care [16].

A bundle approach can be an effective approach for improving care. Experience has also shown that while the bundle approach has worked well and it will helps to improved outcomes in many cases [17].

1.1 **Rationale of Study**

The Care Bundles aim is to development and testing of care bundles, this will helps to generate an effective model of working. This study has also established the value of multidisciplinary health professional groups which is working together for common goal. The use of a care bundle to reduce the postnatal complications in mothers. It is part of a package of interventions to improve patient safety in postnatal care. Postnatal care bundle will be effective in quality care of postnatal period and it will help to early identification and prevention of the postnatal complications.

The Government has taken initiative for delivering a quality care service at all levels of health care service. At a clinical level, this is associated with evidence based practices. However, there is recognizing the gap between research findings and implementation into clinical practice. Developments of new Care bundle are tools that definitely may help in narrow this gap.

The aim of introducing postnatal care bundles into area is to achieve an improvement in outcomes, as:

To develop, test and pilot of Postnatal Care bundle and to assess and evaluate the effectivity of postnatal care bundle for early identification and prevention of postpartum complications among the postnatal mothers.

The objectives of the study is to develop, test & pilot of Postnatal Care Bundle (PN CB) for early identification and prevention of postpartum complications among the postnatal mothers and
2. METHODOLOGY

It is an interventional analytical and a true experimental research design. It will be conducted in AVBRH Sawangi Meghe Wardha.

2.1 Inclusion Criteria

- All postnatal mother who is in first day of postnatal period.
- All postnatal mother delivery by normal.
- Those who are participate willing to the study.

2.2 Exclusion Criteria

- Postnatal mothers who already having postnatal complications.

2.3 Withdrawal Criteria

Mothers will be withdrawn from the study as follows:

1. Want to withdraw from the study on any given time
2. Those who are already having postnatal complication
3. Not fulfilling study schedule.

The reason of withdrawal will be recorded.

2.4 Sample Size

Sample size formula with desired error of margin:

\[ n = \left( \frac{Z^2_{1-\alpha/2} \cdot P \cdot (1-P)}{d^2} \right) \]

Where;

\[ Z_{1-\alpha/2} \] is the level of significance at 5% i.e.
95% confidence interval = 1.96
P - Prevalence of Postnatal complication = 37.55% = 0.3755

\[ d = \text{Desired error of margin} = 7\% = 0.07 \]

\[ n = (1.96^2 x 0.3755 x (1-0.3755)) / 0.07^2 = 183.84 \]

= 185 postnatal mothers needed in the study in each group.

2.5 Study References

Shiv Shankar Sharma, Somen Bhattacharjee, Archanan Kashyap, Ashok Thakur, Sanjay Dubey1, Internal journal of Advances in Medicine, 2018 June 5(3) : 525-529, pISSN-2349-39251 eISSN2349-3933 [18].

2.6 Randomization

All participants are selected by sequentially numbered list at random. The allocation will be isolated for both the group and will be done by assigned research officer.

2.7 Blinding

The participants and care providers not be blinded during the study.

2.8 Interventions

The control group will be provided Standard conventional treatment which is carried out during the postnatal period and the experimental group will receive postnatal care bundle during the postnatal period. Researcher develop, test and pilot of Postnatal Care Bundle (PNCB) for early identification and prevention of postnatal complications among the postnatal mothers and assess the evaluate the effectivity of Postnatal Care Bundle for early identification and prevention of postpartum complications among the postnatal mothers as well as assess conventional postnatal care for early identification and prevention of postnatal complications among postnatal mothers and satisfaction level of staff nurses to be assess after implementation of Postnatal Care Bundle and conventional postnatal care.

2.9 Outcome Measures

Primary outcomes include the develop, test & pilot of Postnatal Care Bundle.

Secondary outcomes involve evaluate the effectivity of Postnatal Care Bundle (PNCB) to early identification and prevention of postnatal complications among postnatal mothers.
Clinical outcomes include the development of postnatal care bundle it will help to early identification and prevention of postnatal complication. This will defiantly help to reduce the mortality and morbidity in the mother as well as newborns and PNCB will be effective in quality care of postnatal period.

2.10 Assessment of Adverse Events

From previous studies, no adverse events were observed. If any complications observed during the study will be recorded and then referred for treatment.

2.11 Data Management and Monitoring

The demographic data, any previous major or minor illness will be recorded when they are enrolled. The conventional treatment which is carried out and implementation of the postnatal care bundle on early identification and prevention of postnatal complications in experimental group during the 6 weeks of postnatal period and to assess the satisfaction level of staff nurses after implementation of Postnatal Care Bundle and conventional postnatal care for early identification and prevention of postpartum complications. Adverse events as well as withdrawals for any reason will be documented.

2.12 Statistical Analysis

Statistical analyses will be done using SPSS software version 22. Routine statistical analysis of mean, standard deviations, frequencies and percentages will be implemented to analyse the clinical data and the outcome measures. T-tests and chi-square tests will be used to measure the difference between pre and post-test groups.
Table1. Study schedule

<table>
<thead>
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<th>Day</th>
<th>0</th>
<th>1st week</th>
<th>2nd weeks</th>
<th>3rd weeks</th>
<th>4th weeks</th>
<th>5th weeks</th>
<th>6th weeks</th>
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<tbody>
<tr>
<td>Time point Allocation &amp; Informed consent</td>
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<tr>
<td>Immediate care of the mother after delivery</td>
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<tr>
<td>Immediate care of the newborn</td>
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<td>Initiation &amp; exclusive Breast feeding</td>
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<tr>
<td>Breast care and Properly Breast feeding</td>
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<td>Assessment of Involution of uterus</td>
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<td>Perineal care</td>
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<td>Episiotomy care</td>
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<td>Postnatal</td>
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<td>Exercise</td>
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</tbody>
</table>

One-way ANOVA will be used to understand the differences between interventions for the period of analysis.

3. EXPECTED OUTCOMES/RESULTS

The study is planned to investigate effectivity of ‘Postnatal care bundle’ for early identification and prevention of postpartum complications among postnatal mothers.

In one study, the use of electronic fetal monitoring (EFM) and placenta praevia care bundle are very success and demonstrates the feasibility of care bundle use in maternity care [19]. Another study in a care bundle is a tool that is very easy to use and easy to audit [20].

4. DISCUSSION

Present study finding will be supported by a systematic review and meta-analysis by Jacqueline F Lavallée, Trish A Gray they suggests that care bundles may reduce the risk of negative outcomes when compared with usual care [21]. A systematic review effects of care bundles on the incidence of ventilator-associated pneumonia in pediatric and neonatal intensive care units? It was showed that the incidences of VAP in mechanically ventilated neonates and children were found to be significantly reduced by the use of ventilator bundles [22]. A observational study on clinical effects of care bundle on patients with traumatic brain injury during nasal feeding by Zhiyue Yan, Hong Chen it was concluded that by applying care bundle to patients with traumatic brain injury, incidence of complications of nasal feeding can be decreased, recovery ability of patients can be strengthened, nutritional status of patients can be improved and the satisfaction degree of patients can be increased [23] Study conducted on impact of Care Bundle on Prevention of Ventilator Associated Pneumonia in an Adult Intensive Care Unit at a Rural Tertiary Teaching Hospital by Anitha Deva, Suresh Kumar Nagaiah et al. it showed that significant reduction in the incidence of VAP rate can be achieved with strict adherence to VAP Care bundle [24].

5. CONCLUSION

Conclusion will be drawn from the statistical analysis.

CONSENT AND ETHICAL APPROVAL

This study is approved by the Institutional Ethics Committee of DMIMS (DMIMS) DU (IEC/2018-19/7601 dated 14/2/2019) All participants will
requested to read and sign the informed consent. The study results will be disseminated to study participants and published in peer-reviewed publications.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. WHO. Technical consultation on postpartum and postnatal care. WHO/MPS/10.03. World Health Organization; 2010
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