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Original Article

Effectiveness of Safe Reduction of Primary Cesarean Birth Patient Safety Bundle

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ABSTRACT

Background: Cesarean section is the most frequent major obstetrical procedure, which carries a higher risk of maternal morbidity and mortality. Implementation of the Safe Reduction of Primary Cesarean Births Safety Bundle should be thoroughly researched in order to reach a remarkable decrease in cesarean section prevalence, promote vaginal delivery and to assess the usefulness of patient safety bundle in decreasing prevalence of cesarean section and promoting vaginal delivery.

Methods: This prospective cohort study was conducted in Department of Obstetrics & Gynecology at Zagazig University Hospitals in Sharkia, Egypt on 180 cases attended to Zagazig University Hospitals. Subjects with primigravida, single fetus and vertex presentation were included in the study. Subjects with multi gravida, multiple feti, fetus with congenital fetal malformation, mal presentation were excluded from the study. Patient safety bundle implemented on all cases who met inclusion criteria. Statistical analysis :

Results: There was significant multivariate correlations between decreasing CS rate and Response, Systems Learning, Recognition and Prevention, and Readiness.

Conclusions: Patient safety bundle has a good effect in decreasing rate of primary caesarian section leading to decrease maternal morbidity and mortality and improving fetal outcome.

Keywords: Safe reduction; Cesarean; Safety bundle.

Declaration of interest

The authors report no conflicts of interest. The authors along are responsible for the content and writing of the paper.

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INTRODUCTION

The most frequent major obstetric surgery is a cesarean section (CS), which involves making incisions in the abdomen and uterine walls to deliver the fetus [1]. Concern is expressed over Egypt's rising cesarean delivery rates. Cesarean births carry higher risks for maternal morbidity and mortality as compared to vaginal births [2].

Approximately 18.6% of people worldwide have CS, with a range of 6 to 27.2%. In North Africa, the average prevalence of CS is 27.8%

[3], with high rate in Egypt (51.8%) [4]. Egypt currently has the second-highest rates of CS in the world, behind only Brazil (55.6%) and the Dominican Republic (56.4%) [3].

According to the most recent 2014 Egypt Demographic and Health Survey (EDHS), CS rates in Egypt have consistently climbed, reaching 52% of all deliveries, mirroring global trends. This represents a more than 100% increase in the CS rate since 2005 [5]. Women who have a cesarean section have a

5- to 20-fold higher risk of infection than those who give birth naturally, making CS the most significant risk factor for postpartum maternal infection [6].

Population-based CS rates higher than 10% are not ideal, according to the World Health Organization's Statement on Caesarean Section Rates [7,8]. Instead, high CS rates could raise maternal risks, negatively affect subsequent pregnancies, and place an undue strain on health services [9,10].

There are many different variables, including both clinical and non-clinical ones, that contribute to the global rise in CS. The growth in CS rates in various settings is attributed to changes in women's risk profiles, an alleged increase in medical indications, as well as non-medical causes such social, cultural, and economic considerations [11,12]. Finding the population's minimum rate for medically needed CS while avoiding medically inappropriate surgery is difficult. This is known as the adequate CS rate. Key professional groups have made it clear that one of their goals is to lower the rate of cesarean deliveries, especially for first-time mothers carrying low-risk infants [13].

In order to lower the rate of cesarean deliveries among nulliparous, term, singleton, and vertex pregnancies, the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine suggested the implementation of evidence-based methods for clinical care improvement and practice culture change [14].

The Safe Reduction of Primary Cesarean Births Patient Safety Bundle, also known as the cesarean bundle, was put together by the Council on Patient Safety in Women's Health Care and is currently being implemented in several hospitals with technical support from the Alliance for Innovation in Maternal Health [13].

The 4 "Rs" (Readiness, Recognition and Prevention, Response, and Reporting and Systems Learning) are the four domains under which all patient safety bundles implemented through (The Alliance for Innovation in Maternal Health) program include a list of evidence-based or evidence informed clinical practice and institutional policy recommendations. Due of their adaptability,

each hospital can decide which bundle components to use and in what order, depending on the local situation [13].

All birthing facilities, healthcare providers, and quality improvement organizations are expected to customize the advice in this bundle to their respective institutions in order to improve performance [15]. In clinical practice, a wide range of tactics are used to improve quality; some are more frequently used (e.g., consensus building, monitoring progress), while others are less frequently used (e.g., introducing financial incentives) [16].

This study's main goal is to describe the state of adoption of the practices suggested in the cesarean bundle at six months. In order to support health systems and healthcare professionals in achieving safe primary cesarean birth rates and promoting vaginal births, which will improve maternal and infant outcomes, the secondary objective is to determine whether hospital characteristics and implementation strategies used are associated with bundle implementation.

METHODS

This prospective cohort study was conducted in Department of Obstetrics & Gynecology at Zagazig University Hospitals in Sharkia, Egypt on 180 cases attended to Zagazig University Hospitals during the period from October 2022 to April 2023.

Subjects with primigravida, single fetus and vertex presentation were included in the study. Subjects with multi gravida, multiple feti, fetus with congenital fetal malformation, mal presentation were excluded from the study.

Written informed consent was obtained from all participants. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving human

Patient safety bundle implemented on all cases who met inclusion criteria as following:

Readiness: We created a team of healthcare professionals and maternity facility that values, supports, and encourages spontaneous beginning and progression of labor and vaginal birth while also being aware of the hazards of cesarean delivery without a valid

medical reason for the current and upcoming pregnancies. Every patient admitted we shared decision making with them and we took informed consent from them that they accepted to continue normal labor and with any complication we will deal with it. We Adopted A provider should get education and training in procedures that increase the possibility of vaginal birth, such as labor evaluation, measures to speed up labor (using oxytocin augmentation), labor support, and pain management (both pharmacologic and non-pharmacologic) by using pethidine or nalufin and non-pharmacologic by help increasing walking during labor that help engagement and decreasing pain)

Recognition and Prevention: We adopted Standardized entry requirements, triage management, education, and assistance for women showing signs of spontaneous labor by assessment cervical dilation, any patient in active phase admitted. We Offered Standardized pain management approaches and comfort measures that accelerate labor and avoid dysfunctional labor (both pharmacologic by using pethidine or nalufin and non-pharmacologic by help increasing walking during labor that help engagement and decreasing pain. We Used conventional methods for determining the fetal heart rate status (using CTG continues during active phase, but this is restricted due to a shortage of devices for all situations, and advocate ways that encourage freedom of movement. In order to lower the likelihood of cesarean delivery, we created standards for the rapid identification of specific issues in patients who could benefit from early intervention (any case with ROM received antibiotics, vaginal bleeding → availability of blood and plasma, fetal distress → availability of NICU).

Response: We tried to help increasing in-house maternity care provider but this limited to few number of cases due to difficult connection and low socioeconomic status of the cases that attend to Zagazig University. cases that not in spontaneous labor we performed standardized induction scheduling by using prostaglandin E2 (dinoglandin) (ROTABIOGEN) more than prostaglandin E 1 (misotac)(SIGMA) but that was limited due to there is no prostaglandin E2 in our hospital

during the period of study. We adopted conventional procedures for handling uterine activity and aberrant fetal heart rate patterns (any abnormality in fetal heart rate during labor appear firstly we stop augmentation then giving IV fluid and putting patient in Lt lateral position. To quickly identify and treat shoulder dystocia, we used standardized, evidence-based labor algorithms, rules, and practices (by ultrasonographic assessment Expected fetal body weight of all cases will be in normal delivery, learning of techniques that helping in delivery of cases with shoulder dystocia). We ensured availability of unique knowledge and methods to reduce the necessity of abdominal delivery.

Reporting/Systems Learning: We performed reports for all cases in this study for helping to evaluate individual provider performance, compare to similar institutions, undertake case review and system analysis to drive care improvement. In order to assess mother and infant outcomes as a result of modifications to labor management strategies for safety, we conducted reports and the necessary balancing measures.

ETHICS APPROVAL

Both the Institutional Review Board and this study's protocol have given their approval [IRB] and the local ethics committee at Zagazig University's Faculty of Medicine.(9895-26/6/2022)

STATISTICAL ANALYSIS

The information was analyzed using SPSS software version 28, 2022 (USA). The mean, standard deviation, or percentage are used to represent the parametric data.

RESULTS

Table 1 shows Distribution of cases according to demographic data; the mean age of cases is 28.4 ± 3.1 ; the mean weight is 71.2 ± 5.5 , and mean BMI is 25.2 ± 2.5 .

Table 2 shows Distribution of cases according to Readiness (Implementation Status at 6 months); according to (building a provider and maternity unit culture); 58 (32.2%) cases haven't started yet, 0 (0%) cases were in the planning stage, 2 (1.11%) cases were partially implemented, 120 (66.6%) cases were Fully Implemented During Collaborative, and 0 (0%) cases Fully Implemented Before Collaborative. According to (Optimizing

patient and family engagement); 55 (30.5%) cases haven't started yet, 10 (5.5%) cases were in the planning stage, 5 (2.77%) cases were partially implemented, 110 (61.11%) cases were Fully Implemented During Collaborative, and 0 (0%) cases Fully Implemented Before Collaborative. According to (Adopting provider education and training techniques); 51 (28.3%) cases haven't started yet, 12 (6.6%) cases were in the planning stage, 6 (3.3%) cases were partially implemented, 111 (61.67%) cases were Fully Implemented During Collaborative, and 0 (0%) cases Fully Implemented Before Collaborative.

Table 3 shows that according to (Implementing standardized admission criteria); 56 (31.1%) cases haven't started yet, 2 (1.11%) cases were in the planning stage, 3 (1.6%) cases were partially implemented, 119 (66.11%) cases were Fully Implemented During Collaborative, and 0 (0%) cases Fully Implemented Before Collaborative. According to (Offering standardized techniques of pain management); 50 (27.7%) cases haven't started yet, 8 (4.44%) cases were in the planning stage, 6 (3.2%) cases were partially implemented, 116 (64.4%) cases were Fully Implemented During Collaborative, and 0 (0%) cases Fully Implemented Before Collaborative. According to (Using standardized methods in the assessment of the fetal heart rate); 45 (25%) cases haven't started yet, 10 (5.55%) cases were in the planning stage, 5 (2.7%) cases were partially implemented, 120 (66.7%) cases were Fully Implemented During Collaborative, and 0 (0%) cases Fully Implemented Before Collaborative. According to (Adopting protocols for timely identification of specific problems); 38 (21.11%) cases haven't started yet, 12 (6.66%) cases were in the planning stage, 3 (1.6%) cases were partially implemented, 127 (70.5%) cases were Fully Implemented During Collaborative, and 0 (0%) cases Fully Implemented Before Collaborative.

Table 4 shows that according to (Having available an in-house maternity care provider); 2 (1.11%) cases haven't started yet, 2 (1.11%) cases were in the planning stage, 3 (1.6%) cases were partially implemented, 45

(25%) cases were Fully Implemented During Collaborative, and 130 (72.2%) cases Fully Implemented Before Collaborative. According to (Upholding standardized induction scheduling); 1 (0.5%) cases haven't started yet, 8 (4.4%) cases were in the planning stage, 6 (6.6%) cases were partially implemented, 40 (22.2%) cases were Fully Implemented During Collaborative, and 126 (70%) cases Fully Implemented Before Collaborative. According to (Utilizing standardized evidence-based labor algorithms); 3 (1.66%) cases haven't started yet, 10 (5.5%) cases were in the planning stage, 5 (2.7%) cases were partially implemented, 45 (25%) cases were Fully Implemented During Collaborative, and 121 (67.2%) cases Fully Implemented Before Collaborative. According to (Adopting policies that outline standard responses to abnormal fetal heart rate); 2 (1.11%) cases haven't started yet, 12 (6.6%) cases were in the planning stage, 3 (1.66%) cases were partially implemented, 51 (28.3%) cases were Fully Implemented During Collaborative, and 114 (63.3%) cases Fully Implemented Before Collaborative. According to (Making available special expertise and techniques to lessen the need for abdominal delivery); (0) cases haven't started yet, 5 (2.7%) cases were in the planning stage, 4 (2.2%) cases were partially implemented, 49 (27.2%) cases were Fully Implemented During Collaborative, and 122 (67.7%) cases Fully Implemented Before Collaborative

Table 5 shows that according to (Tracking and reporting labor and cesarean measures in sufficient detail); 1 (0.5%) case haven't started yet, 2 (1.11%) cases were in the planning stage, 4 (2.2%) cases were partially implemented, 44 (24.4%) cases were Fully Implemented During Collaborative, and 130 (72.2%) cases Fully Implemented Before Collaborative. According to (Tracking appropriate metrics and balancing measures); 1 (0.5%) case haven't started yet, 3 (1.6%) cases were in the planning stage, 5 (2.7%) cases were partially implemented, 43 (23.8%) cases were Fully Implemented During Collaborative, and 129 (71.6%) cases Fully Implemented Before Collaborative.

Table 6 shows that there was significant

Univariate Correlations between Decreasing CS rate and Readiness, Recognition and Prevention, Response, and Reporting/Systems Learning. There was significant Multivariate Correlations between Decreasing CS rate and Readiness, Recognition and Prevention, Response, and Reporting/Systems Learning.

Table 7 shows that 49 of our cohort had CS while 131 had Normal delivery. 84 of our Control had CS while 96 had Normal delivery.

Table 8 shows that 119 out of 180 had Spontaneous labor while 90 out of 119 had Normal delivery. 29 out of 119 had CS in 29 cases that had CS 15 cases had fetal distress

and 15 cases had obstructed labor and 6 cases had vaginal bleeding.

Table 9 shows that 119 cases out of 180 cases had Spontaneous labor while 61 out of 180 had Induction of labor. 30 out of 61 had fetal distress, 20 out of 61 had CS while 10 out of 61 had vaginal bleeding.

Table 10 shows that cost of CS in our hospital 2000 EGP ,and cost of VD 1100 EGP ,annual cost of CS before safety bundle 336000 EGP ,annual cost of CS after safety bundle 196000 EGP ,annual cost saving relationship 63000 EGP .cost involve only materials not including health care provider’s fees or rooming of cases.

Table 1: Distribution of cases according to demographic data

| | |
|-------------------------------|------------|
| Age, years | |
| Mean ± SD | 28.4 ± 3.1 |
| Minimum - Maximum | 18-35 |
| Weight, Kg | |
| Mean ± SD | 71.2 ±5.5 |
| Minimum – Maximum | 62.5-86.5 |
| BMI, Kg /m² | |
| Mean ± SD | 25.2 ±2.5 |
| Minimum - Maximum | 20-28 |

Table 2: Distribution of cases according to Readiness (Implementation Status at 6 months).

| | Not Started | Planning Stage | Partially Implemented | Fully Implemented During Collaborative | Fully Implemented Before Collaborative |
|--|--------------------|-----------------------|------------------------------|---|---|
| Readiness | | | | | |
| 1.Build a provider and maternity unit culture | 58 (32.2%) | 0 | 2 (1.11%) | 120 (66.6%) | 0 |
| 2.Optimize patient and family engagement | 55 (30.5%) | 10 (5.5%) | 5 (2.77%) | 110 (61.11%) | 0 |
| 3.Adopt provider education and training techniques | 51 (28.3%) | 12 (6.6%) | 6 (3.3%) | 111 (61.67%) | 0 |

Table 3: Distribution of cases according to Recognition and Prevention (Implementation Status at 6 months).

| | Not Started | Planning Stage | Partially Implemented | Fully Implemented During Collaborative | Fully Implemented Before Collaborative |
|--|-------------|----------------|-----------------------|--|--|
| Recognition and Prevention | | | | | |
| 1.Implement standardized admission criteria | 56 (31.1%) | 2 (1.11%) | 3 (1.6%) | 119 (66.11%) | 0 |
| 2.Offer standardized techniques of pain management | 50 (27.7%) | 8 | 6 (3.2%) | 116 (64.4%) | 0 |
| 3.Use standardized methods in the assessment of the fetal heart rate | 45 (25%) | 10 | 5 (2.7%) | 120 (66.7%) | 0 |
| 4.Adopt protocols for timely identification of specific problems | 38 (21.11%) | 12 | 3 (1.6%) | 127 (70.5%) | 0 |

Table 4: Distribution of cases according to Response (Implementation Status at 6 months).

| | Not Started | Planning Stage | Partially Implemented | Fully Implemented During Collaborative | Fully Implemented Before Collaborative |
|---|-------------|----------------|-----------------------|--|--|
| Response | | | | | |
| 1.Have available an in-house maternity care provider | 2 (1.11%) | 2 (1.11%) | 3 (1.66%) | 45 (25%) | 130 (72.2%) |
| 2.Uphold standardized induction scheduling | 1 (0.5%) | 8 (4.4%) | 6 (6.6%) | 40 (22.2%) | 126 (70%) |
| 3.Utilize standardized evidence-based labor algorithms | 3 (1.66%) | 10 (5.5%) | 5 (2.7%) | 45 (25%) | 121 (67.2%) |
| 4.Adopt policies that outline standard responses to abnormal fetal heart rate | 2 (1.11%) | 12 (6.6%) | 3 (1.66%) | 51 (28.3%) | 114 (63.3%) |
| 5.Make available special expertise and techniques to lessen the need for abdominal delivery | 0 | 5(2.7%) | 4 (2.2%) | 49 (27.2%) | 122 (67.7%) |

Table 5: Distribution of cases according to Reporting/Systems Learning (Implementation Status at 6 months).

| | Not Started | Planning Stage | Partially Implemented | Fully Implemented During Collaborative | Fully Implemented Before Collaborative |
|---|-------------|----------------|-----------------------|--|--|
| Reporting/Systems Learning | | | | | |
| 1.Track and report labor and cesarean measures in sufficient detail | 1 (0.5%) | 2 (1%) | 4 (2.2%) | 44 (24.4%) | 130 (72.2%) |
| 2. Track appropriate metrics and balancing measures | 1 (0.5%) | 3 (1.6%) | 5 (2.7%) | 43 (23.8%) | 129 (71.6%) |

Table 6: Univariate and multivariate correlations between Decreasing CS rate and different factors

| Univariate Correlations | | Value |
|----------------------------|--------------|---------|
| Readiness | Correlation | 0.342 |
| | Significance | <0.0001 |
| Recognition and Prevention | Correlation | 0.470 |
| | Significance | <0.0001 |
| Response | Correlation | 0.411 |
| | Significance | <0.0001 |
| Reporting/Systems Learning | Correlation | 0.355 |
| | Significance | <0.0001 |
| Multivariate Correlations | | |
| Readiness | Correlation | 71.31 |
| | Significance | <0.0001 |
| Recognition and Prevention | Correlation | 20.492 |
| | Significance | <0.0001 |
| Response | Correlation | 25.590 |
| | Significance | <0.0001 |
| Reporting/Systems Learning | Correlation | 72.30 |
| | Significance | <0.0001 |

Table [7]: Distribution of cases according to outcomes

| | Cohort |
|-----------------|--------|
| CS | 49 |
| Normal delivery | 131 |

DISCUSSION

According to our study, there was a substantial correlation between readiness (Build a provider and maternity unit culture-Optimize) and decreasing CS patient and family engagement- provider education and training techniques).

. About 50% Subjective indicators including labor arrest disorders (18%) and an unrelaxing fetal state have been linked to the rise in primary cesarean deliveries in the United States during the past 20 years (32%) [17, 18]. Both diagnoses are dependent on the provider, highlighting the importance of labor support to prevent dysfunctional labor and lower cesarean delivery rates in addition to demonstrating how practice style, providers'

decision-making, and unit culture influence cesarean delivery rates.

According to our analysis, there was a substantial difference between lowering CS and Recognition and Prevention (adopting uniform admission standards).Offer standardized pain management strategies, use standardized fetal heart rate testing techniques, and adopt guidelines for early detection of specific issues.

Numerous studies have shown that admitting women who are in latent labor increases the likelihood of cesarean birth and other interventions. 34 percent of initial cesarean births are the result of abnormal labor progression. Based on Zhang's research, one criterion for the active stage of labor was redefined as 6-cm dilatation rather than 4 cm,

which reinforces the case against admitting women in pre-active labor who haven't shown labor progress (less than 6-cm dilatation) early. This method is suggested to lower the likelihood that nulliparous women would undergo a cesarean delivery and increase their happiness with the birthing process [15].

Analysis has shown that approximately one fourth to one third of the increase in the current primary cesarean birth rate is the result of procedures that are performed for concerning fetal heart rate patterns. Improper interpretation of continuous electronic fetal monitoring tracings and miscommunication can cause unnecessary cesarean births [19].

According to our analysis, there was a considerable distinction between decreasing CS and Response.

(Available an in-house maternity care provider - standardized induction scheduling - standardized evidence-based labor algorithms- policies that specify typical reactions to an abnormal fetal heart rate - available specialized knowledge and methods to reduce the necessity for an abdominal delivery)

Recent studies demonstrate a considerable decrease in cesarean delivery rates following the adoption of midwife-laborist models [20].

A retrospective cohort investigation comparing women who have an induction to those who go into spontaneous labor reveals a roughly two-fold increase in cesarean delivery rates for those whose labors were induced. [21].

According to our investigation, there was a considerable distinction between lowering CS and Reporting/Systems Learning.

Track relevant metrics and balancing measures (Track and report labor and cesarean measures in adequate detail)

Effective cesarean birth reduction programs have not had any unfavorable outcomes, such as decreased Apgar scores or an increase in admissions to neonatal intensive care units as a result of cesarean birth reduction. But for the initiative and modifications to safely reduce cesarean births, institutions must monitor balancing measures and metrics of safety outcomes for women and infants [22].

After implementation of safety bundle rate of caesarian section 27% in comparison to rate of caesarian section all over Egypt In Egypt, CS rates have consistently risen to 72% of all

deliveries. Compared to the global average, the caesarian section rate after the introduction of safety bundle 27 is higher. Approximately 18.6% of people worldwide have CS, with a range of 6 to 27.2%. The typical CS rate in North Africa is 27.8% [3].

Rate of caesarian section after implementation of safety bundle 27% in comparison to rate of caesarian section according to WHO, The World Health Organization (WHO) has released fresh information showing that the number of caesarian sections performed worldwide has increased and now accounts for more than one in five (21%) deliveries. According to the study, this number is expected to rise over the following ten years, with nearly a third (29%) of all births projected to occur by caesarian section by 2030 [23].

After implementation of safety bundle we decreased CS rate and cost, according to our hospital annual cost saving 63000 EGP for decreasing primary Cs and cost include only materials not include health care provider's fees and rooming of cases and we can decrease cost by 900 EGP per 1 case.

In relation to other private hospitals in zagazig (A,C,B) average cost of Cs 6000 EGP and average cost VD 3500 EGP and if we implement safety bundle in this hospitals we can decrease cost by 2500 EGP per 1 case .

CONCLUSIONS

Our assessment has promising results, and patient safety bundle has a good effect in decreasing rate of primary caesarian section that leading to decrease maternal morbidity and mortality and improving fetal outcome. Clinicians should be aware of this variability and get more involved in cesarean birth bundle practices, which can reduce costs at our hospital by reducing primary Cs.

Conflicts of interest: None.

Financial Disclosure : None

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