

# Observational Descriptive Study of Clinical Outcomes on Extremely Obese Pregnant, Nulliparous Women Carrying a Single Term Fetus in Vertex Presentation (NTSV)

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**Abstract:** Obesity is a prime example of a non-contagious condition that has reached pandemic proportions. Efforts by the World Health Organization to establish standards of care for this population have not met with universal acceptance. Female obesity during the reproductive years has been consistently reported in association with adverse events, both for the mother and the fetus with short- and long-term health effects on both, including and not limited to cardiac disease, obesity and early death.

The effects of obesity are seen early in the reproductive period and are a continuum during prenatal care and delivery. Extreme maternal obesity is consistently reported in association with dysfunctional labor and increased risk for cesarean delivery and certain complications like post-partum hemorrhage and surgical site infection. We report a contemporaneous analysis of a limited cohort of nulliparous, extremely obese women with body mass index (BMI)  $\geq 50$  K/m<sup>2</sup>, delivering at term ( $\geq 37$  weeks gestation), carrying a single live normal fetus in vertex presentation (NTSV). These patients have been cared for by a limited number of board-certified obstetrical providers, in one institution. These patients were selected because they are considered candidates for an effort at safely reducing the cesarean rate. The results observed indicate a higher incidence of induction of labor, followed by failed induction of labor and delivery by cesarean compared with extant literature in the non-obese population. These results may represent a local practice that may not be generalizable to other geographic practice locations or a true decreased ability to reduce cesarean delivery in extremely obese pregnant women that merits additional considerations.

We encourage multi-institutional well conducted studies to determine if this population should be differentially considered as NTSV-XTO and reported as a separate group.

**Keywords:** Obesity in pregnancy, morbid obesity, extreme obesity, super obesity, massive obesity.

## INTRODUCTION

Obesity has reached worldwide pandemic proportions with adverse effects in public health. Within this spectrum, maternal obesity is estimated to have reached 31.8 % among women aged 20 to 39 years with a quarter of these women falling within class III obesity [1]. Epidemiological studies conducted in the last century assessed the associations between obesity and obstetric complications. The World Health Organization (WHO) and the National Institute of Health (NIH) in the United States defined the standard classification utilizing the Body Mass Index (BMI) [2]. This metric represents the relationship between the patient's weight over its height per meter square ( $W/H^2$ ) and is reported as K/m<sup>2</sup> (Table 1). The maternal body mass index has been reported as significantly associated with delivery route in term nulliparous and multiparous women with and without a previous cesarean delivery [3]. As obesity in pregnancy represents a serious and increasing public health concern with short and long-term implications for the

mother and her offspring, the quality of maternity care provided for this group of patients needs full understanding. Evidence based standards for prenatal care must be utilized in this population to optimize clinical obstetric and neonatal outcomes [4]. While early screening for obesity is still an incomplete clinical accomplishment [5], obesity itself has had an impact on our nation's health and our social perceptions of acceptability. It has been reported that obstetrical providers may not adhere uniformly to the monitoring of gestational weight gaining and other variables when treating obese and non-obese pregnant women [6]. Many women have expressed their desire for the conversation to focus on the medical issues brought upon during preconception counseling or while they are pregnant [7]. Our goal is to report on the obstetrical outcome as a result of interventions by a limited number of qualified providers.

In 1992, Perlow *et al.* [8] reported on the perinatal outcomes of massively obese pregnant women. They defined that group as patients weighing 300 pounds and above while pregnant. This paper was one of the first to outline the complications and comorbidities associated with this level of maternal obesity, which

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included an increased risk of primary cesarean section, macrosomia, intrauterine growth retardation, and neonatal admission to the intensive care unit [8]. Recently, research has outlined additional comorbidities which includes increased risk of fetal anomalies except gastroschisis, certain maternal malignancies and early death. Preconception counseling, prenatal care, labor monitoring, delivery and postpartum care in the extremely obese pregnant women may need a clear understanding of the physiologic differences and demands of the increasing body mass with requirements that differ from the non-obese population.

**Table 1: Definitions of Obesity**

<b>OBESITY DEFINITIONS</b>	
National Institutes of Health (USA) World Health Organization	
<b>Body Mass Index (BMI) = <math>W/H^2</math> or <math>K/m^2</math></b>	
	<b>BMI</b>
• Recommended Weight	18.5 to 24.9 $K/m^2$
• Overweight	25.0 to 29.9
• Obesity	$\geq 30$
Class I	30 to 34.9
Class II	35 to 39.9
Class III (morbid obesity)	$\geq 40$
with comorbidities	$\geq 35$
• <b>Super (extreme) obesity (9%)</b>	<b><math>\geq 50</math></b>

The report addresses the opportunity to reduce cesarean delivery rate among the extremely obese ( $BMI \geq 50 K/m^2$ ) within an identified low risk population consisting of nulliparous women delivering at term, a singleton fetus in vertex presentation (NTSV). In 2010, The US Department of Health and Human Services established national goals to reduce the rate of cesarean section among low risk women in its Healthy People 2020 initiative [9]. A low-risk female, as defined by the organization, is a full-term (at least 37 weeks since the first day of the last normal menstrual period) singleton pregnancy, with a vertex fetus which is commonly referred to as NTSV. This goal involves decreasing our cesarean section rate among the NTSV population from a baseline rate of 26.5% in 2007 to 23.9% by 2020 [9]. Based on these initiatives, beginning in 2020 The Joint Commission along with the National Quality Forum (NQF) will begin publicly reporting accredited hospitals with consistently high (>30%) cesarean birth rates among NTSV patients based on the Perinatal Care Measure (PC-02) [10]. Although this effort is considered clinically relevant by many organizations supported by a number of clinical initiatives, we must also identify any patient subgroup

in which a decrease in the rate of cesarean could pose a significant health risk for either mother or fetus.

Our effort seeks to challenge these efforts to safely reduce cesarean rates among extremely obese patients. The objective of the study is to describe the clinical outcomes of extremely obese NTSV patients cared in one birthing center by a limited number of obstetrical providers. We identify this group as NTSV-XTO. The report reflects the care provided by a group of obstetricians and may not be generalizable to other institutions or geographic areas. By bringing more awareness to the issue of extreme obesity in pregnancy in the light of the American College of Obstetricians and Gynecologists (ACOG) goal, we intend to emphasize the need to identify certain pregnant women cohorts that by virtue of their presenting clinical characteristics may not allow for safely reducing the cesarean rate.

## METHODS

This is a contemporaneous observational analysis of prospectively collected medical records reporting a limited case series which included 115 pregnant women with BMIs  $\geq 50 K/m^2$ , (ICD-10 099214) defined as extreme obesity (XTO). All the patients included in the review are nulliparous, with term pregnancies, single live normal fetus in the vertex presentation (NTSV). Forty extremely obese non NTSV parturients were excluded.

All subjects received cared from a limited number of Board-Certified Obstetricians as attending physicians or in a supervisory role for physicians in training in a teaching hospital not an academic center. All patients were followed during their prenatal care, labor, delivery, and for a period of 6 weeks postpartum. All conceptions were unassisted. Once the previously established clinical parameters were obtained, the patients were deidentified. Due to the relatively small sample of the cohort there was no apriori statistical sample size calculated for the study.

All patients received prophylactic intravenous antibiotics via a second-generation cephalosporin and azithromycin within 60 minutes from the incision.

Regional anesthesia epidural or intradural was utilized except in 4 cases where it was not feasible after three attempts. In those cases, general anesthesia with endotracheal intubation was employed.

At the time of the cesarean the abdominal pannus was handled as per the attending obstetrician clinical judgment and displaced either cephalad, caudad or upwards according to its size. Lower limbs intermittent pressure devices were applied for thromboprophylaxis.

A self-retaining retractor/incision protector, the O device (Alexis™. Applied Medical Rancho Santa Margarita, Cal. 92688. USA) was utilized at the discretion of the senior surgeon.

Active management of the third stage of labor was utilized via intravenous oxytocin at the time of delivery of the anterior shoulder or after the delivery of the placenta. At the decision of the surgeon the oxytocin IV drip was continued for 4 hours post cesarean in certain patients.

Prophylactic post delivery anticoagulation was utilized according to physician's preference. Those patients received 5,000 units of fractionated heparin twice daily starting 12 hours post cesarean or 8 hours post vaginal delivery until discharge.

Approval was obtained from the institution IRB (ref. 031696 2019-137).

## RESULTS

The findings observed in the study subjects were compared with similar variables in the non-obese population extracted from extant relevant literature

115 patients (22 %) were included in the review. 16 % of the patients delivered more than once following the index pregnancy. Two patients remain undelivered. Two patients were lost to follow up. Fifty per cent were Black, 45 % were white and 5 % belong to different ethnic backgrounds.

Approximately 27% of the patients were classified as isolated obesity [12]; 14.7 % showed carbohydrate intolerance and 25.2 % either hypertension or preeclampsia. Gestational hypertension was the predominant diagnosis for which the patients were induced; none of those patients received consistent antihypertension treatment.

Induction of labor was initiated in 44 patients (44.1 %) , and 22 were diagnosed with failed induction of labor ending in cesarean delivery (44.3%). There was no standard institution definition for failed induction of labor and the decision for cesarean delivery was made by the attending/supervising obstetrician.

There were 83 cesarean deliveries; the observed cesarean section rate was 74.7 % at an adjusted rate of 55.5%. The expected cesarean rate was 23.9%. A Pfannestiel incision was performed in 86.7 % of the patients. Alternative skin incisions were performed at the decision of the surgeon (Supra and infraumbilical, Joel Cohen, Mayllard). Vacuum extraction was utilized in 6.8% of cesareans; There were 3 cases of shoulder dystocia (3.1%), 2 during a cesarean, 1 during a vaginal delivery. Time of skin incision to hysterotomy ranged from 5 to 24 minutes (on a 636 lbs patient, 22 cm from skin to uterus), average 9 minutes. The "O" device was utilized in 35 patients (47%). Surgical site disruption (SSI) was observed in 14 patients (12.6%) and were equally found in patients on whom the O retractor was or was not utilized (Table 2).

Abdominal dressing was utilized at the preference of the surgeon. Pressure dressing was the most frequently employed, a single use prophylactic negative pressure wound therapy system (PICO 7, Smith and Nephew Inc. Brookfield, Conn. USA. CPT code 97607, 97608) was applied in 10.8 % of patients.

There were 6 maternal readmissions (5.4%) within 30 days. Four due to an SSI, one secondary to a lower limb deep vein thrombosis and pulmonary embolism and one secondary to acute onset of respiratory failure with need for invasive assisted ventilation secondary to bacterial pneumonia.

Neonatal weight was over 4,000 g in 11.5 % and above 4,500 gm in 5.2 % of newborns. Neonatal weight below 2,500 g was found in 6.3 % of the cases.

There were no fetal, maternal or neonatal deaths during the observation period and no maternal deaths occurred within 365 days from delivery.

## DISCUSSION

In a birth center that represents the most common environment for obstetric practice and training in the United States we observed in a group of 111 extremely obese pregnant NTSV women that they were 2.4 times more likely to undergo a cesarean delivery

Similar to the present report, multiple studies have found a significant association between super obesity and cesarean section [14,15-21]. Our adjusted rate of cesarean section is similar to the rates Alanis *et al.* [19] (55.5% vs 56.0%) and Garabedian *et al.* [18] (55.5% vs 56.1%) reported while researching perinatal outcomes among women with extreme obesity (BMI > 50 K/m<sup>2</sup>).

**Table 2: Cohort Characteristics and Results**

Cohort Characteristics		
Maternal age (years)	18-46	27.5±5.12
Body Mass Index (BMI) K/m <sup>2</sup>	≥50 - 106	56.9 ±7.79
Gestational age (weeks)	39 ±1.3	
Ethnicity		
Black American	58 / 50 %	
White	52 / 45 %	
Other	5 / 3%	
Isolated extreme obesity	27%	
Carbohydrate intolerance	17/ 14.7 %	
Bronchial asthma, OSA, GERD*	38/ 33.0 %	
Hypertension/ Preeclampsia	29/ 25.2 %	
Delivery ≥40 weeks EGA	40/21.6 %	
Delivery ≥41 weeks EGA	3/2.7%	
Induction of labor	49 / 44.1%	
Failed Induction of labor	22 / 44.8 %	
Observed Cesarean delivery	83 / 74.7%	
"O" self-retaining retractor	35/ 47.9%	
Vacuum extraction	5 / 4.5 %	
Vaginal delivery	28 / 25.2 %	
Shoulder dystocia	5 / 4.5 %	
Post-partum hemorrhage	5/ 4.5 %	
Spontaneous abortion	3 / 3%	
Surgical site infection	11/ 15%	
Maternal readmission w/30 days	6 /5.4%	
Lost to f/u	3	
Neonatal variables		
Apgar score 1 min < 5	12/ 10%	
Birth weight (grams)	3382±608	
Large for gestational age ≥4K.	11/ 11.5 %	
Large for gestational age ≥4.5K	5 / 5.2%	
Small for gestational age <2.5K	7/6.3 %	

\*OSA. Obstructive sleep apnea. GERD. Gastroesophageal reflux disease.

Similarly, a population-based cohort study conducted by Marshall *et al.* [17] on nulliparous super obese pregnant women recorded a rate of cesarean section that was below the rate we observed (55.5% vs 74.7%). The consistency of our findings compared to previous studies implies that even among a lower risk group within this cohort, the rate of cesarean section is still significantly higher than the general population and is comparable to a general super obese population. This additional clinical information complements other studies and points to the difficulty in the task to safely

reduce the cesarean rate. However, additional research is necessary to outline any significant differences between NTSV extremely obese (XTO) women and the general pregnant obese population.

There was no standardized institutional protocol to initiate induction of labor or an established definition for the diagnosis of failed induction of labor (FIOL). The rates of induction of labor among the superobese population have been inconsistent throughout the literature but all outline a significant statistical

association between induction of labor and increasing BMI [16,18,20,21].

A study conducted by Knight *et al.* [21] using United Kingdom hospital surveillance data outlined extremely obese women (BMI >50) were more likely to undergo induction of labor (adjusted OR 1.97; 95% CI 1.53–2.54), but less likely to labor (adjusted OR 0.38; 95% CI 0.28–0.50). Knight *et al.* [21] reported an induction rate lower to our study (37.6% vs 44.1%). Garabedian *et al.* [18] reported an independent association of induction of labor with cesarean delivery and obesity, the strength of association does not appear to change with increasing BMI. It has been outlined that labor induction among the morbidly obese (BMI>40) requires higher doses of oxytocin and prostaglandins, with an increased likelihood of cesarean deliveries performed for failed induction and failure to progress in the higher BMI categories [22]. Although this study is not specific to our population, failure to progress has been reported to be an indication for cesarean among the superobese population [23].

It has been hypothesized that the high rates of cesarean section and FIOl in superobese women are due to physiological differences in the course of labor. Perlow *et al.* [15] recorded a prolonged delivery interval for massively obese women. Years later other workers recorded a slower progression of labor with increasing BMI, especially among nulliparous women [24].

We noted a 9.6% of cesareans were diagnosed as emergency. Considering the additional steps needed in these population, including our finding of an average 9 minutes to reach the uterus once the patient and the team are ready to proceed, a very tight and dynamic risk assessment must be utilized to prospectively understand the potential added risk for a rapid delivery.

Partographs have been variably utilized to record the progression of labor, providing clinicians with a pictorial overview of the process [25]. As an example, a partograph recorded on an extremely obese women in our study outlined the prolonged latent phase compared to a morbidly obese patient (BMI 40 – 49 K/m<sup>2</sup>) with a difference of 3 hours (9.5 hours vs 6 hours). It has been observed that women who had partographs with a latent phase were more likely to receive a cesarean section than a partograph without a latent phase (RR 2.45, 95% CI 1.72 to 3.50) [25].

Although it is difficult to make concrete conclusions based on this limited data, we propose the

development of standard partographs both for spontaneous and induced labor that can be utilized to better understand the differences in labor progression across different strata of BMI, specifically above 50 K/m<sup>2</sup> and allow for improve clinical decisions and patient counseling.

Significant literature has been published assessing the proposed pathophysiology causing women of higher BMI to undergo a prolonged labor. A study conducted by Verdiales *et al.* [26] found that obese women (BMI > 35 K/m<sup>2</sup>) have a significantly higher rate of arrest of dilation compared to individuals of a normal BMI (BMI <26 K/m<sup>2</sup>). This finding has been linked to the altered metabolic condition associated with obesity [27,28]. Ultimately, many of these physiological findings have been linked to dysfunctional interactions of oxytocin with its receptor within uterine myometrium [27].

Furthermore, elevated levels of cholesterol have been linked to inhibition of calcium channels, subsequently leading to decreased force of contraction [29,30]. Concurrently, it has been found that elevated leptin also exerts an inhibitory effect on oxytocin induced myometrial contractions, leading to decreased frequency and amplitude of contractions [31]. It seems that the functional discrepancies in the development of labor among obese mothers can be attributed to these aforementioned pathophysiological differences. It is important to understand the specific characteristics of labor among the extremely obese in order to establish appropriate clinical management for this unique population.

We also recorded a number of comorbidities and pregnancy complications associated with our study that could begin to explain the high rates of cesarean section among this population. We observed hypertension and preeclampsia among 25 % of our cohort, a value consistent with previous data [17,19,20]. Importantly the most frequent diagnosis that was utilized to decide an induction of labor was gestational hypertension, in the absence of active therapy or demonstrated clinical or laboratory findings.

Although the definition of macrosomia and large for gestational age (LGA) is inconsistent across several studies, multiple papers have established a positive relationship between maternal BMI and birth weight [8,16,19,20,32]. An elevated BMI has been found to be associated with prolonged gestation (>40 weeks), but has not been reported among the super obese

population [33]. Among women who underwent primary cesarean section in our study 21.6 % reached 40 weeks and 2.7 % got to 41 weeks without signs of spontaneous labor.

Similarly, previous studies have shown an increased risk of wound infection among the superobese [16,21]. However, given the small sample size and lack of robust statistical data on these particular values, it can be difficult to make generalizations about the NTSV extremely obese population based on our data alone.

Potential limitations of our study include the small sample size extracted from a single tertiary care institution. Thus, the finding in our study may be limited to institutions similar to that studied in the current investigation. Given the refined nature of our cohort, only 111 patients qualified after the appropriate exclusion criteria was applied, 2 remained undelivered. However, given the lack of research on the NTSV extreme obese population it is difficult to determine the generalizability of our data. Our study also fails to offer comparative statistics with a non-obese cohort managed by the same staff which leads to extrapolation based on previous data and a lack of ability to make strong statistical claims. The time interval that takes to accumulate a significant number of study subjects with the needed characteristics, militates against the chance for one single institution to reach an adequate number of subjects for meaningful statistical analysis. Recently a multiinstitutional workshop which included the National Institute of Child Health and Human Development discussed the use of cesarean delivery rate as a quality care measure without considering the case mix of the study population, including nulliparity as a risk factor for cesarean and some efforts to tailor compensation on NTSV cesarean rates without consideration for potential maternal and neonatal consequences [33]. We propose future research addressing these gaps to offer insight on these issues. Additionally, there was no standard treatment protocols; consequently, all clinical decisions were made at the direction of the attending obstetrician.

Despite these limitations, our study is one of the first to explore extreme obesity among the NTSV population and offers insight into considerations that should be made when managing this challenging population.

Significant efforts are in place to safely reduce the cesarean rate in a segment of the parturient population considered at low risk; nulliparous patients, at term,

with a single live normally grown fetus and vertex presentation. In the presence of an increasing frequency of extremely obese patients, with or without identifiable co-morbid conditions, a clear understanding of the variables posed during labor and delivery must be factored in. Based on these findings, it can be extrapolated that standardization of prenatal care and delivery needs to be adjusted to account for the higher rates of cesareans and complications among these patients. Those adjustments may include transfer those patients to maternity centers where a trained team applies standard principles for labor monitoring and strict indications for cesarean delivery in the absence of demonstrable maternal or fetal pathology. A standardized team approach, use of adequate equipment and instrumentation are paramount to decrease any additional risks during the labor, delivery and postpartum period, along with access to surgical consultations, maternal intensive care settings and neonatal intensive care unit.

We recommend classifying these patients as NTSV-XTO and develop, test and clinically apply a partograph to assist in understanding the differences in physiologic labor modified by extreme obesity, so to be able to follow the efforts at safely reducing cesarean deliveries. Standard nomenclature and procedures to accomplish the goal of safely reducing the cesarean rate must be in place. We encourage multidisciplinary, multi-institutional, multinational efforts in order to test the feasibility of reaching an optimal and safe cesarean delivery rate in this challenging population.

Widely disseminated public and health practitioners information programs to clearly address the health and economic cost of obesity at all levels may represent a proactive approach to reduce its rate with the objective of improving the maternal-infant health dyad short and long term.

## CONFLICTS OF INTEREST

The authors have reported no conflicts of interest

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