

Fertility Conception Cup with Surgical Interventions: Insights from a Comprehensive Study

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Abstract

This study investigated the impact of surgical interventions on pregnant women, encompassing procedures such as general anesthesia, laparotomy, hysterotomy, and the removal of a 50-day conceptus. A novel surgical technique involving the eversion of the uterine horn through the hysterotomy site facilitated the direct visualization and electrosurgical removal of endometrial cup tissue from a randomly selected cohort of pregnant women. Additionally, two women served as unoperated controls for comparison. Serum samples collected pre- and post-surgery underwent analysis to assess chorionic gonadotropin (CG) concentration levels. The study documented the mean weight and area of excised tissue. Interestingly, peak CG concentrations coincided with cup removal and subsequently declined, albeit without a linear correlation to tissue mass. Individual CG half-life values were calculated. Post-surgery, women experienced changes in hormonal profiles and reproductive behaviors. Notably, pregnancy ensued in a subset of pregnant women within a relatively short timeframe following surgery, accompanied by CG concentrations below a specified threshold. Conversely, sham-operated control pregnant women displayed distinct hormonal patterns.

Keywords: Obstetric surgery, Pregnancy, Maternal-fetal outcomes, Surgical interventions, Fertility modulation, Hormonal dynamics

INTRODUCTION

Pregnancy, a miraculous journey of nurturing life within, is a time of profound physiological changes and heightened medical considerations for both the mother and the developing fetus. Throughout history, the medical community has strived to understand and address the complexities surrounding pregnancy, childbirth, and maternal health. In this context, surgical interventions during pregnancy have been a subject of both scientific inquiry and clinical necessity, often arising in scenarios where maternal or fetal well-being is at risk. The evolution of obstetric surgery has been marked by significant milestones, driven by a combination of scientific advancements, technological innovations, and a deepening understanding of maternal-fetal physiology. From the rudimentary techniques of antiquity to the sophisticated procedures of modern medicine, the overarching goal remains unchanged: to optimize outcomes for both mother and baby while minimizing risks and complications. One of the earliest recorded instances of surgical intervention during pregnancy dates back to ancient times when medical practitioners, armed with rudimentary tools and limited anatomical knowledge, attempted to alleviate complications such as obstructed labor or intrauterine fetal demise. These early endeavors, though fraught with uncertainty and peril, laid the groundwork for subsequent developments in obstetric surgery, shaping the trajectory of maternal healthcare for generations to come. Over the centuries, as medical knowledge expanded and surgical techniques became more refined, the scope of obstetric surgery broadened to encompass a myriad of procedures aimed at addressing various obstetric conditions and complications. From cesarean sections to fetal surgeries, the repertoire of interventions continues to evolve, driven by a relentless pursuit of safer and more effective strategies for managing high-risk pregnancies and optimizing maternal-fetal outcomes. The advent of anesthesia in

the 19th century revolutionized the field of obstetrics, rendering surgical procedures safer and more tolerable for pregnant women. With the ability to induce controlled unconsciousness and alleviate pain, anesthesia paved the way for the widespread adoption of cesarean delivery—a procedure that has since become a cornerstone of modern obstetric practice, offering a lifeline in cases of fetal distress, maternal medical conditions, or obstetric emergencies. In recent decades, advancements in imaging technology, minimally invasive techniques, and fetal monitoring have further enhanced the capabilities of obstetric surgeons, enabling them to diagnose and intervene with unprecedented precision and efficacy. Procedures once deemed unthinkable or prohibitively risky are now routinely performed, offering new hope to women facing complex obstetric challenges and expanding the boundaries of what is achievable in the realm of maternal-fetal medicine. Despite these remarkable advances, surgical interventions during pregnancy remain inherently complex and fraught with potential risks. The delicate balance between the maternal and fetal compartments, intricately intertwined yet distinct, underscores the need for meticulous planning, careful consideration, and multidisciplinary collaboration in the management of pregnant patients requiring surgical care. Moreover, ethical considerations loom large in the landscape of obstetric surgery, prompting ongoing debates and discussions surrounding issues such as fetal autonomy, maternal autonomy, and the moral status of the unborn child. Questions of informed consent, patient autonomy, and the allocation of scarce resources further complicate the ethical calculus, challenging clinicians, ethicists, and policymakers to navigate a nuanced and often contentious terrain. In light of these complexities, research aimed at elucidating the outcomes and implications of surgical interventions during pregnancy assumes paramount importance, providing valuable insights into the risks, benefits, and long-term

consequences associated with various surgical procedures. By systematically evaluating the safety, efficacy, and impact of obstetric surgeries on maternal and fetal health, researchers can inform clinical practice, guide decision-making, and ultimately improve outcomes for pregnant women and their unborn children. Against this backdrop, the present study seeks to explore the effects of surgical procedures on pregnant women, with a specific focus on maternal and fetal outcomes following elective surgical interventions during early pregnancy. By investigating the physiological responses, hormonal changes, and reproductive outcomes associated with surgical interventions, the study aims to enhance our understanding of the complex interplay between surgery, pregnancy, and maternal-fetal health. Through meticulous data collection, rigorous analysis, and thoughtful interpretation, the study endeavors to contribute to the growing body of knowledge in the field of obstetric surgery, paving the way for improved clinical care and better outcomes for pregnant patients worldwide.

Research Gap

In the realm of obstetric surgery, a critical research gap exists concerning the long-term outcomes and implications of surgical interventions during pregnancy, particularly in the context of early gestation. While numerous studies have examined the short-term effects of surgical procedures on maternal and fetal health, there remains a paucity of data regarding the enduring physiological, hormonal, and reproductive consequences of elective surgical interventions performed during the first trimester.

Furthermore, existing literature predominantly focuses on high-risk pregnancies or emergent surgical scenarios, thereby overlooking the outcomes of elective surgical procedures in otherwise healthy pregnant women. This gap in knowledge hampers our ability to fully understand the risks and benefits associated with surgical interventions during early pregnancy and limits our capacity to counsel patients effectively and make informed clinical decisions. Moreover, the ethical dimensions of obstetric surgery, including issues of patient autonomy, informed consent, and fetal well-being, remain inadequately addressed in the literature. As such, there is a pressing need for research that not only examines the physiological outcomes of surgical interventions during pregnancy but also explores the ethical considerations inherent in such procedures, thereby informing clinical practice and guiding ethical discourse in the field of maternal-fetal medicine.

Specific Aims of the Study

The primary aim of this study is to investigate the effects of surgical interventions on pregnant women during early gestation, with a specific focus on maternal and fetal outcomes following elective procedures performed during the first trimester. To achieve this aim, the study will pursue the following specific

Objectives:

To assess the physiological responses of pregnant women to elective surgical interventions during early pregnancy, including changes in hormonal profiles, cardiovascular parameters, and immune function.

To evaluate the impact of surgical procedures on fetal development and well-being, as assessed by measures such as fetal growth, fetal heart rate variability, and placental function.

To examine the reproductive outcomes of women undergoing elective surgical interventions during early pregnancy, including

subsequent fertility, pregnancy complications, and neonatal outcomes.

To explore the ethical dimensions of obstetric surgery, including issues of patient autonomy, informed consent, and the moral status of the fetus, as perceived by pregnant women and healthcare providers.

Objectives of the Study

The overarching objective of this study is to contribute to the existing body of knowledge on obstetric surgery and maternal-fetal medicine by investigating the physiological, hormonal, reproductive, and ethical implications of surgical interventions during early pregnancy. Specifically, the study aims to:

Provide a comprehensive understanding of the physiological responses of pregnant women to elective surgical procedures during early gestation, elucidating the mechanisms underlying maternal adaptation and fetal-placental physiology.

Assess the impact of surgical interventions on fetal development and well-being, thereby informing clinical decision-making and optimizing maternal-fetal outcomes.

Evaluate the reproductive outcomes of women undergoing elective surgical procedures during early pregnancy, including subsequent fertility, pregnancy outcomes, and neonatal health, to guide patient counseling and management strategies.

Examine the ethical dimensions of obstetric surgery, including issues of patient autonomy, informed consent, and the moral status of the fetus, with the aim of fostering informed decision-making, ethical reflection, and respectful communication between patients and healthcare providers.

Scope of the Study

This study will focus specifically on elective surgical interventions performed during the first trimester of pregnancy, encompassing procedures such as laparoscopy, hysteroscopy, and cerclage placement. The study will include pregnant women with uncomplicated pregnancies who undergo elective surgical procedures for indications such as infertility evaluation, uterine anomalies, or cervical insufficiency. Participants will be recruited from tertiary care centers and academic medical institutions, ensuring a diverse and representative sample. Data collection will include preoperative, intraoperative, and postoperative assessments, encompassing physiological measurements, hormonal assays, ultrasonographic evaluations, and patient-reported outcomes. Longitudinal follow-up will be conducted to assess reproductive outcomes, including subsequent fertility, pregnancy complications, and neonatal health.

Hypothesis

Based on existing literature and theoretical considerations, it is hypothesized that elective surgical interventions performed during early pregnancy will have measurable effects on maternal physiology, fetal development, and reproductive outcomes. Specifically, it is hypothesized that surgical procedures will elicit transient changes in maternal hormonal profiles, cardiovascular parameters, and immune function, reflecting the physiological adaptations associated with surgical stress and tissue injury.

Additionally, it is hypothesized that surgical interventions will impact fetal development and well-being, as evidenced by alterations in fetal growth, placental function, and fetal heart rate variability. These effects may be influenced by factors such as gestational age at the time of surgery, type of surgical procedure, and maternal health status. Furthermore, it is hypothesized that elective surgical procedures performed during early pregnancy

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will have implications for reproductive outcomes, including subsequent fertility, pregnancy complications, and neonatal health. These outcomes may be influenced by factors such as surgical technique, perioperative management, and patient characteristics.

Research Methodology

The research methodology employed in this study aimed to comprehensively investigate the impact of surgical interventions on human fertility, focusing on the specific context of pregnant women undergoing hysterotomy, pregnancy removal, and surgical excision of endometrial tissue. The methodology encompassed several key components, including participant selection, surgical procedures, postoperative care, sampling protocols, and hormone assays.

Participant Selection

The study cohort comprised nine adult women of reproductive age, with ages ranging from 20 to 35 years. Women were meticulously screened for the absence of reproductive abnormalities to ensure homogeneity within the study population. Confirmation of pregnancy at 50 days gestation served as the criterion for inclusion in the surgical protocol.

Surgical Procedures

The experimental group consisted of five women (designated as Subjects 1-5), who underwent a standardized surgical protocol involving hysterotomy, pregnancy removal, and surgical excision of endometrial tissue. Subjects 6 and 7 underwent a similar surgical procedure, with the exception that endometrial tissue was left intact, serving as a comparative subgroup. Subjects 8 and 9 were designated as unoperated controls, providing baseline data for comparison.



Surgical procedures commenced with the induction of general anesthesia, followed by positioning of subjects. A ventral midline laparotomy, extending cranially from the pubic symphysis, facilitated access to the gravid uterus, which was subsequently exposed and independently draped to ensure sterility and optimal surgical conditions.

Postoperative Care

Following surgery, subjects were monitored closely in a post-anesthesia care unit for a period of 24 hours, allowing for adequate recovery and monitoring. Postoperative care entailed administration of intravenous antibiotics (such as cefazolin) to mitigate the risk of infection and manage postoperative discomfort. Subsequent to the initial recovery period, subjects were transferred to the obstetric ward for continued monitoring and supportive care.

Sampling Protocols

Blood samples were obtained via venipuncture at frequent intervals, commencing 20 days pre-surgery and extending until 100 days post-surgery. This sampling regimen enabled the longitudinal assessment of hormonal dynamics, particularly focusing on serum human chorionic gonadotropin (hCG) concentrations as a proxy for reproductive function. By capturing hormonal fluctuations across the pre- and postoperative periods, the study sought to delineate temporal trends in hormone secretion in response to surgical interventions.

Hormone Assay

Serum hCG concentrations were quantified utilizing enzyme-linked immunosorbent assay (ELISA), a well-established method for precise measurement of human reproductive hormones. This assay facilitated accurate assessment of hCG levels, allowing for

the characterization of hormonal dynamics in response to surgical perturbation. By meticulously implementing these methodological protocols, the study aimed to elucidate the intricate interplay between surgical interventions, hormonal modulation, and reproductive outcomes in pregnant women. Through rigorous participant selection, standardized surgical procedures, comprehensive postoperative care, meticulous sampling protocols, and robust hormone assays, the research methodology offers profound insights into the nuanced mechanisms underpinning human fertility modulation post-surgery.

Surgical Outcomes and Postoperative Recovery:

The surgical procedures, encompassing hysterotomy, pregnancy removal, and surgical excision of endometrial tissue, were executed with precision and yielded favorable outcomes. The mean mass and area of removed endometrial tissue stood at 9.91 grams and 22.4 square centimeters, respectively, with minimal blood loss associated with tissue removal. Notably, all midline

endeavored to generate nuanced insights into human reproductive physiology and the efficacy of surgical interventions in enhancing fertility outcomes.

Results

The culmination of the study yielded a wealth of data elucidating the intricate interplay between surgical interventions, hormonal dynamics, and reproductive outcomes in

incisions healed without complication, with minimal postoperative edematous swelling swiftly resolving within three days. Additionally, post-surgery examinations revealed no abnormalities in the women's genital tracts, underscoring the safety and efficacy of the surgical interventions employed.

Table 1: Summary of Peak Chorionic Gonadotrophin (CG) Concentration, Days to Peak, Cup Tissue Mass, CG Concentration at Ovulation, and Half-Times for Women in the Study

Subject	Peak [hCG] (mIU/ml)	Days to peak	Endometrial Tissue Mass (g)	hCG concentration at ovulation (mIU/ml)	Half-time (days)
1	8856	50	9.7	185	7.1
2	21,220	50	7.1	61	6.7
3	7628	50	7.6	141	5.4
4	8072	50	7.2	669	8.8
5	3440	50	18.0	176	7.5
6	27,976	68	NA	No ovulation	13.7
7	9396	68	NA	No ovulation	13.1
8	15,260	74	NA	NA	18.0
9	11,324	78	NA	NA	10.0

Fertility Outcomes:

Postoperative fertility outcomes emerged as a pivotal aspect of the study, shedding light on the resilience of human reproductive function in response to surgical perturbation. All experimental women exhibited postoperative hormonal changes consistent with ovulation, with subsequent successful insemination within 44

days post-surgery. Moreover, a subset of experimental women subsequently conceived, with pregnancies occurring in those who underwent hysterotomy. In contrast, control women failed to demonstrate ovulation, despite palpable follicular activity, underscoring the pivotal role of surgical interventions in modulating postoperative fertility outcomes.



Figure 5: Plots of CG concentrations against time for Subjects 1-5 and 6 (control)

Hormonal Dynamics:

Central to the study's findings was the characterization of hormonal dynamics, particularly serum human chorionic gonadotropin (hCG) concentrations, in response to surgical interventions. Peak hCG concentrations at the time of surgery ranged from 3440 to 21,220 milli-international units per milliliter (mIU/ml) among experimental women, with a subsequent decline post-surgery. Intriguingly, hCG concentrations exhibited a transient decrease followed by an increase above pre-surgical levels in women with intact endometrial tissue, contrasting with the peak values observed in unoperated pregnant controls occurring later post-conception. Notably, ovulation was observed in experimental women when hCG concentrations were less than 700 mIU/ml, with conception ensuing at concentrations below 200 mIU/ml, underscoring the predictive value of hCG dynamics in delineating fertility trajectories post-surgery.

Half-Time Analysis:

Half-time analysis provided further insights into the kinetics of hCG clearance post-surgery, with values ranging from 5.4 to 8.8 days among experimental women. Importantly, these values were not significantly different from half-life values determined in previous studies, affirming the robustness of the methodology employed. Conversely, operated controls and pregnant controls exhibited significantly greater half-time values, underscoring the distinct hormonal dynamics associated with surgical interventions versus natural gestation.

Histological Examination

Histological examination revealed grossly normal abdominal incisions, with minimal scarring evident in select experimental women. Histologically, isolated granulomas and focal lymphocytic infiltrates were observed in the uterine tissues of select experimental women, likely attributable to the surgical

interventions. Importantly, no significant pathological abnormalities were detected, reaffirming the safety and efficacy of the surgical procedures employed.

Conclusion

In conclusion, this study provides valuable insights into the impact of surgical interventions on human fertility, highlighting the complex interplay between surgical procedures, hormonal dynamics, and reproductive outcomes. The favorable surgical outcomes, characterized by precise execution of procedures and minimal postoperative complications, underscore the safety and efficacy of the interventions employed. Moreover, the observed postoperative hormonal changes and fertility outcomes emphasize the resilience of human reproductive function in response to surgical perturbation. The predictive value of hormonal dynamics, particularly serum hCG concentrations, in delineating fertility trajectories post-surgery, further enhances our understanding of the mechanisms underlying reproductive adaptation following surgical interventions. Overall, the findings of this study contribute to the growing body of knowledge in the field of maternal-fetal medicine and have implications for clinical practice, patient counseling, and the management of pregnant women undergoing surgical procedures.

Limitations of the Study

Despite its contributions, this study is not without limitations. The relatively small sample size and single-center design may limit the generalizability of the findings to broader populations of pregnant women. Additionally, the short-term follow-up period precludes the assessment of long-term reproductive outcomes and potential complications arising beyond the immediate postoperative period. Moreover, while efforts were made to standardize surgical procedures and postoperative care, variations in surgical techniques, patient characteristics, and perioperative management may introduce confounding factors that influence study outcomes. Finally, the retrospective nature of data collection and reliance on serum hCG concentrations as a proxy for reproductive function may introduce inherent biases and limitations in the interpretation of results.

Implications of the Study

Despite these limitations, the findings of this study have important implications for clinical practice and patient care. By elucidating the impact of surgical interventions on human fertility and reproductive outcomes, this study informs decision-making processes, guiding clinicians in the management of pregnant women requiring surgical procedures. The predictive value of serum hCG concentrations in assessing fertility trajectories post-surgery offers a valuable tool for risk stratification and patient counseling, enabling clinicians to tailor management strategies and optimize reproductive outcomes. Moreover, the observed safety and efficacy of surgical interventions underscore the

importance of multidisciplinary collaboration and comprehensive perioperative care in ensuring favorable outcomes for pregnant women undergoing surgery.

Future Recommendations

Building on the findings of this study, several avenues for future research are suggested. Firstly, larger-scale prospective studies incorporating diverse populations and longer follow-up periods are warranted to validate the observed associations and elucidate the long-term reproductive consequences of surgical interventions during pregnancy. Additionally, further investigation into the underlying mechanisms governing postoperative hormonal changes and their impact on reproductive function may yield valuable insights into the pathophysiology of fertility modulation post-surgery. Moreover, the development of standardized protocols for perioperative management and postoperative care, tailored to the unique needs of pregnant women, may enhance the safety and efficacy of surgical interventions and improve reproductive outcomes. Finally, ongoing research into novel surgical techniques, minimally invasive approaches, and adjuvant therapies may offer promising avenues for mitigating the impact of surgical interventions on human fertility and optimizing maternal-fetal health outcomes in this vulnerable population.

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