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Enhancing maternal safety: evaluating the impact of systematic temporary uterine artery clamping in cesarean sections on maternal health

Submission date
20/11/2023

Recruitment status
No longer recruiting

Registration date
06/12/2023

Overall study status
Completed

Last Edited
20/09/2024

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Cesarean sections, the most common abdominal surgical intervention globally, have witnessed increasing rates, reaching 32.1% in the USA by 2021. The associated blood loss, often double that of vaginal delivery, poses challenges, leading to prolonged hospital stays and maternal illness. Postpartum hemorrhage (PPH) during cesarean sections remains a significant concern, causing 1-10% of deliveries and contributing to maternal death rates. Current prevention strategies, primarily non-surgical, include uterotonic drugs and uterine massage. Surgical techniques such as uterine artery ligation have been effective in managing PPH. This study focuses on a new surgical approach involving temporarily clamping the uterine arteries during cesarean sections. Findings suggest that this technique significantly reduces blood loss, shortens hospital stays, and lowers the risk of anemia after childbirth. While promising, more extensive studies are needed to confirm these benefits and explore wider applications. The hope is that this method could enhance the well-being of mothers undergoing cesarean deliveries.

Who can participate?
Pregnant women aged 18 to 45 years, with a gestational age between 34 and 42 weeks, undergoing cesarean sections at the Regional University Hospital of Malaga

What does the study involve?
Participants are randomly allocated to one of two groups to be treated with either uterine artery clamping or the standard procedure. Blood loss during surgery is measured in both groups.

What are the possible benefits and risks of participating?
Patients undergoing the clamping technique showed reduced blood loss, shorter hospital stays, and lower anemia prevalence at discharge compared to the control group. Benefits include enhanced recovery and potential cost savings. Specific risks associated with the clamping technique are not explicitly mentioned.

Where is the study run from?
Regional University Hospital of Malaga (Spain)

When is the study starting and how long is it expected to run for?
October 2019 to February 2025

Who is funding the study?
Regional University Hospital of Malaga (Spain)

Who is the main contact?
Rosa Gomez, rosa.gomez@ibima.eu

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
1729-N-23

Study information

Scientific Title
Systematic temporary clamping of the uterine arteries for the prevention of bleeding during cesarean section: the results of implantation on maternal morbidity

Acronym
STAB-PCS

Study objectives
To evaluate whether a surgical technique based on temporary bilateral clamping of both uterine arteries could reduce uterine blood flow during cesarean sections and thus prevent blood loss.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/11/2023, Provincial de Málaga - Comité de Ética de la Investigación (Av. de Carlos Haya, 84, Málaga, 29010, Spain; +34 (0)951 29 00 00; eticainvestiga.hch.sspa@juntadeandalucia.es), ref: 1729-N-23

Primary study design
Interventional

Study design
Longitudinal prospective randomized controlled study

Study type(s)
Prevention, Quality of life, Safety, Efficacy

Health condition(s) or problem(s) studied
Prevention of heavy bleeding during cesarean section

Interventions
Simple randomization is a method of random assignment in which each participant has an equal probability of being assigned to any of the study groups. Group 1 consists of individuals born in even-numbered years (subjected to clamping), while Group 2 consists of those born in odd-numbered years (subjected to standard procedure).

In the study group, after fetal extraction and delivery of the placenta, the uterus was exteriorised in order to clearly expose both uterine arteries and avoid injuries to neighboring structures. Both uterine arteries were temporarily compressed approximately 2 cm below the hysterotomy using an atraumatic vascular clamp (i.e., a DeBakey artery clamp). Once the correct placement of the clamp had been verified, the cavity was checked and the hysterotomy was sutured. Both in the study group and in the control group, the hysterorrhaphy technique was performed using continuous monolayer sutures. It was planned that the clamping time would not exceed 10 min, and in the case where it did, intermittent decompression would be used. Once the hysterorrhaphy had been performed, both vascular clamps were removed after verifying a correct hemostasis. After removing the clamps, the area of application was inspected to verify that no accidental anatomical injury had occurred. Finally, the uterus was reintroduced into the abdominal cavity, and the cesarean section was completed according to the usual technique.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Hemoglobin values measured prior to surgery and 24 h post-surgery. Determination of hemoglobin in blood/results in personalized record of analytical results in patient history at hospital center.

Key secondary outcome(s)
1. Puerperal complications: the presentation of alterations or the presence of fever, pains, bleeding, or any eventuality recorded in the clinical history or clinical records. Evaluated at the

time of clinical discharge and at the time of presentation collected in the clinical history.
2. Presence of anemia and, if so, its severity: the classification of the severity of post-surgical anemia is generally performed based on the amount of hemoglobin in the blood and associated clinical symptoms. Assessed in the analytical controls carried out 24 hours after cesarean section.
3. Transfusion of hematological derivatives required: general classification with an indication of units of hemoglobin to transfuse, although it is important to note that these figures may vary according to specific medical guidelines and practices. Based on analytical parameters and post-surgical hemoglobin levels.
4. Days of admission after the cesarean section: collected from the admission and discharge records of the patients at the time of discharge from the hospital.

Completion date
28/02/2025

Eligibility

Key inclusion criteria
1. Pregnant woman
2. Aged between 18 and 45 years
3. Gestational ages of between 34 and 42 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Key exclusion criteria
The researchers did not consider adopting any exclusion criteria based on risk factors for hemorrhagic disease since their initial objective was to evaluate the effectiveness of this technique also in this type of patient. Except for non-acceptance by the patient.

Date of first enrolment
25/11/2023

Date of final enrolment
30/12/2024

Locations

Countries of recruitment
Spain

Study participating centre
Regional Universitario Málaga Hospital
Avenida Arroyo de los Angeles s/n
Málaga
Spain
29010

Sponsor information

Organisation
Hospital Regional Universitario de Málaga

ROR
https://ror.org/01mqsmm97

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Regional Universitario Málaga

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Manuel Gomez (manugocas@hotmail.com) and Lorena Sabonet (lorenasabonet@gmail.com). The data will be available in the first quarter of 2024. Consent from participants was required and obtained.
The study adheres to all fundamental characteristics of patient anonymization in clinical studies. The participants' identities are strictly protected, and only the principal investigator is aware of them. This approach ensures the confidentiality and privacy of the patients, aligns with ethical and legal requirements, prevents discrimination, safeguards information security, and encourages participation in the research. Additionally, it contributes to the integrity of the

research by basing results on objective data and facilitates scientific collaboration by allowing secure information sharing among researchers and collaborators without compromising patient confidentiality.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/09/2024	20/09/2024	Yes	No