Study protocol entitled “Preoperative measurement of abdominal circumference as a predictor of difficult spinal anesthesia and maternal hypotension during caesarian section”

Version January 2024

I. Introduction:

Spinal anesthesia is now the anesthetic technique of choice for cesarean section, responsible for a considerable reduction in maternal morbidity and mortality. However, physiological changes during pregnancy contribute to the difficulty of the technique and the occurrence of complications such as arterial hypotension with maternal-fetal impact. Accurate prediction of technical difficulty and occurrence of hypotension could improve clinical decision-making, modify management and facilitate early intervention with adequate preoperative preparation.

The objective of this study is to validate the measurement of abdominal circumference as an easy and available clinical tool for the prediction of difficult spinal anesthesia and the occurrence of arterial hypotension in an obstetric context.

II. Study characteristics

- Type of study: prospective observational
- Location of the study: Gyneco-obstetrical operating room of the Mother-Child Hospital Mohammed VI University Hospital of Marrakech
- Principal investigators: Professor Ahmed Rhassane El Adib / Professor Essafti Meryem / Dr Nde Ngala Marina
- Inclusion criteria: Patients admitted to the operating room of the Mother and Child Hospital for a cesarean section.
- Exclusion criteria:
    - Extremely urgent Caesarean section for fetal bradycardia/Cord prolapse
    - Scoliosis.
    - Contraindication to spinal anesthesia.
    - History of spine surgery

- ❖ Conduct of the study: The study will not lead to any change in the care administered to patients, it will be conducted as follows:

Inclusion of patients after having informed them of the characteristics of the study and obtained their consent.

Measurement of the abdominal perimeter in the lying and sitting position in the operating room and ultrasound identification of the level corresponding to the Tuffier Line with measurement of the skin-medullary canal distance in the same position as for carrying out the spinal anesthesia procedure.

Clinical assessment of visibility and palpation of the spinous processes

Carrying out spinal anesthesia according to the usual protocols with a standardized dose and injection technique by the same experienced anesthetist.

Recording the number of attempts made, reorientations of the needle at each skin puncture, and the occurrence of immediate complications (traumatic CSF).

Verification of motor and sensory levels (thermal pain sensitivity) using standardized scales

Recording of anticipated adverse effects: post-spinal anesthesia arterial hypotension and its onset time and vasopressor requirements

Collection of clinical demographic data anonymously using an information sheet (appendix 1)

III. The potential dangers incurred by the subjects

This study does not entail any risk since it is based solely on the measurement of a clinical parameter which is the abdominal perimeter with a tape measure without causing damage or delaying the care of parturients.

Other than measuring abdominal circumference, the use of ultrasound is considered harmless, being a non-invasive, non-irradiating examination which poses no danger to the parturient or the fetus.

IV. Conditions for protecting the confidentiality of patient data

Medical data concerning patients is subject to medical confidentiality and any data noted in the information sheet is only identifiable through a digital identifier assigned to patients upon inclusion. The protection of all medical data is a priority, the participant will be identified by a code number (IP) without resorting to personal or initial nominations. This data may be transmitted to the various entities participating in the study under strict conditions ensuring their confidentiality.