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How using ultrasound technology to guide the administration of an erector spinae plane block affects individuals undergoing a specific type of surgery called modified radical surgery for breast cancer

Submission date 06/03/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 08/03/2024	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 08/03/2024	**Condition category** Surgery	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The research set out to examine how using ultrasound to guide a procedure called erector spinae plane block (ESPB) affects the stability of blood pressure and heart rate, as well as the management of pain after surgery in individuals having a specific type of breast cancer surgery under general anesthesia. Furthermore, it aimed to explore how ESPB influences the amount of pain-relieving medications and anesthetics used during the surgery and recovery period.

Who can participate?
Female patients aged 50-65 years undergoing modified radical surgery for breast cancer due to a breast tumor

What does the study involve?
Patients were divided into two groups using a random process. In the first group (GA group), patients received general anesthesia for their surgery. In the second group (GA+ESPB), patients received both general anesthesia and an ultrasound-guided erector spinae plane block before the start of anesthesia. The patients were monitored continuously from the end of the surgery until 24 hours later.

What are the possible benefits and risks of participating?
Participation in this study will not have any impact on the patient's health status, and the patient will not have any advantage or disadvantage by participating in this research. By participating in the study, the patient is not exposed to any risk, as the same preoperative preparation, surgical treatment, and monitoring methods are used as for those who do not participate in the research. The application of the interfascial erector spinae block involves a simple procedure, a low risk of complications, and provides analgesia for up to 24 hours. Patients themselves may not directly benefit from participation, except for systematic additional monitoring of pain

levels and recording of the researched parameters. The study may be beneficial for future female patients undergoing radical surgical interventions for breast cancer. Considering literature data indicating that approximately 60% of women complain of severe acute pain after breast cancer surgery, and the fact that anesthesia can influence the progress of surgical treatment by suppressing the strong stress response and its harmful consequences on the body, thereby affecting the course and outcome of patient treatment in terms of prolonged hospitalization, increased morbidity, and mortality, the study aims to identify clinical parameters and parameters of metabolic, hormonal, and inflammatory response triggered in the body during radical breast cancer surgeries. The study focuses on the impact of the interfascial erector spinae block in combination with general anesthesia on the clinical, metabolic, hormonal, and inflammatory response of the body during breast cancer surgery.

Where is the study run from?
University clinical center of Nis (Serbia)

When is the study starting and how long is it expected to run for?
December 2022 to November 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
35797/4

Study information

Scientific Title
The impact of ultrasound-guided erector spinae plane block on hemodynamic stability and postoperative pain in patients undergoing modified radical surgery for breast cancer

Study objectives
The study aimed to evaluate the effects of ultrasound-guided erector spinae plane block (ESPB) on hemodynamic stability and postoperative pain control in patients undergoing modified radical surgery for breast cancer under general anesthesia. Additionally, it aimed to investigate the impact of ESPB on perioperative opioid and anesthetic consumption.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/12/2022, Ethics Committee of the University Clinical Center Niš (Dr. Zoran Djindjic Boulevard 48, Nis, 18000, Serbia; +381 506906; etickiodbor@gmail.com), ref: 35797/4

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other, Quality of life, Treatment

Health condition(s) or problem(s) studied
The impact of ultrasound-guided erector spinae plane block on hemodynamic stability and postoperative pain in patients undergoing modified radical surgery for breast cancer

Interventions
Study Design
In our prospective, comparative study, 48 female patients aged 50-65 years undergoing modified radical surgery for breast cancer due to a breast tumor were included. Limiting the sample to the age group of 50-65 years was aimed at reducing variability among participants, striving to achieve homogeneity in biological and physiological characteristics, including hormonal status related to the population. Written informed consent was obtained from all patients at least 24 hours prior to participation. A consecutive series of patients operated on from January 2023 to October 2023 were included in the study after signing informed consent forms.

Study Groups
The study included two groups. Patients were randomly assigned to two groups in an alternate sequence 1, 2. The first group (GA group) underwent general anesthesia during the surgical procedure, while the second group (GA+ESPB), in addition to general anaesthesia, received ultrasound-guided erector spinae plane block before the induction of anesthesia. The total duration of monitoring the patients was from the completion of the surgery until the next 24 hours.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Hemodynamic parameters (heart rate, systolic, diastolic, and mean arterial pressure) were continuously monitored using the Mindray iPM 12 monitor and recorded in 10 time intervals: T0 - baseline values, T1 - before induction of anesthesia, T2 – after induction of anesthesia, T3 – before surgical incision, T4 – 5 minutes after incision, T5 - 15 minutes af-ter incision, T6 - 25 minutes after incision, T7 - 35 minutes after incision, T8 – before the conclusion of the operation, T9 – after awakening from anesthesia. The percentage devia-tion from baseline values was calculated for each patient, and the frequency of variations exceeding 20% from baseline values was registered. Cardiovascular system stability was assessed as follows: Grade I - 0-10% deviation from baseline values; Grade II - 11-20%; Grade III - 21-30%; Grade IV - more than 30% deviation from baseline values.
2. To assess the degree of pain in the postoperative period, a visual analog scale (VAS) for pain was used, and the VAS score was recorded. VAS scores were measured at 5 time intervals: first in the post-anesthesia care unit 30 minutes after waking up and completing the surgery, then at 2, 6, 12, and 24 hours after waking up and completing the surgery.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/11/2023

Eligibility

Key inclusion criteria
1. Female patients with confirmed breast cancer
2. Aged 50 to 65 years
3. Indication for radical surgery for breast cancer
4. American Society of Anesthesiologists (ASA) score of 1 to 2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Upper age limit
65 years

Sex
Female

Total final enrolment
48

Key exclusion criteria
1. Refusal of the patient to participate in the study
2. Unsuccessful administration of the erector spinae plane block (ESPB)
3. Known allergy to the used drugs
4. Local infection at the injection site
5. Unable to cooperate
6. Deemed to have mental deficits and morbid obesity (BMI > 40 kg/m²)

Date of first enrolment
05/01/2023

Date of final enrolment
25/10/2023

Locations

Countries of recruitment
Serbia

Study participating centre
University Clinical Center Niš
Dr. Zoran Djindjic Boulevard 48
Nis
Serbia
18000

Sponsor information

Organisation
University of Nis

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are available from the corresponding author on email (draleksandarnikolic@hotmail.com) upon reasonable request.

IPD sharing plan summary

Available on request, Other