ISRCTN10515707 https://doi.org/10.1186/ISRCTN10515707

Retrospective analysis of the medical records of large cervical fibroids

Submission date
22/11/2024

Recruitment status
No longer recruiting

Registration date
25/01/2025

Overall study status
Completed

Last Edited
13/01/2025

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Large cervical fibroids are non-cancerous growths in the uterus that can cause symptoms like heavy bleeding, pain, and frequent urination, significantly affecting women's quality of life. This study investigates how preoperative factors, such as age, weight, and symptoms, influence recovery outcomes after surgery for large cervical fibroids. The goal is to improve recovery times and guide personalized care for future patients.

Who can participate?
Women aged between 18 to 65 years with fibroids larger than 8 cm and complete clinical data

What does the study involve?
The study reviews medical records of 152 patients treated between 2018 and 2022. It compares recovery outcomes such as hospital stay, pain levels, and complications between those who had laparoscopic surgery and open surgery, alongside analyzing their preoperative health data.

What are the possible benefits and risks of participating?
As this is a retrospective observational study, there are no direct benefits or risks to participants. However, the findings may help improve surgical planning and recovery care for future patients.

Where is the study run from?
Women's Hospital School of Medicine Zhejiang University, China

When is the study starting and how long is it expected to run for?
Data collection covering surgeries performed from 2018 to 2022

Who is funding the study?
Natural Science Foundation of Zhejiang Province, China

Who is the main contact?
Dr Xiaoyong Li, lixiaoyongdyx@zju.edu.cn, China

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Xiaoyong Li

ORCID ID
http://orcid.org/0009-0004-7425-1491

Contact details
Women's Hospital, School of Medicine, Zhejiang University
Hangzhou
China
310006
+86-15990131962
Lixiaoyongdyx@zju.edu.cn

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The impact of preoperative physiological indicators on postoperative recovery time and rehabilitation outcomes in patients undergoing surgery for large cervical fibroids

Study objectives
The hypothesis of this study is that preoperative physiological indicators significantly influence postoperative recovery time and rehabilitation outcomes in patients undergoing surgery for large cervical fibroids. Specific preoperative factors such as age, BMI, gravidity, and urinary frequency are expected to correlate with critical postoperative recovery metrics, including:

Duration of hospital stay,
Pain levels (measured by VAS scores),
Time to first mobilization,
Complication rates.
The study proposes that these indicators could help predict recovery outcomes and guide individualized surgical planning and postoperative management, optimizing recovery speed and minimizing complications

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/08/2022, Ethics Committee of Women's Hospital School of Medicine Zhejiang University (1 Xueshi Road, Lakeside Shangcheng District, Hangzhou, 310000, China; +86-0571-89992355; zjpwhh@zju.edu.cn), ref: IRB-20220280-R

Study design
A retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Large cervical fibroids

Interventions
This study does not involve active interventions as it is observational.

Participants and Study Design
This retrospective cohort study included 152 patients who underwent surgery for large cervical fibroids (≥8 cm) at a single hospital from 2018 to 2022. Patients aged 18 to 65 years with complete clinical data were enrolled. Exclusion criteria included severe comorbidities, pregnancy, malignant uterine tumors, or incomplete clinical records.

Intervention and Follow-up
Preoperative Assessment: Patients underwent medical evaluations, including ultrasound, blood tests, and physiological assessments (e.g., age, BMI, gravidity, parity, urinary symptoms) before surgery.

Surgery: Patients underwent either open myomectomy or laparoscopic myomectomy, with the surgical method selected based on clinical judgment. Surgery-related data (duration, blood loss, fibroid count, and transfusions) were recorded.

Postoperative Care: Patients were monitored for pain (VAS score), mobilization time, time to first flatus, and complications. Blood tests were repeated to track changes in biochemical markers (e.g., Hb, WBC, NEU%, CRP).

Observation and Follow-up Period
Total Observation Time: From hospital admission to discharge, with a median hospital stay of 5.5 days (IQR 4-6 days).

Total Follow-up Time: Follow-up continued throughout the hospital stay until discharge, during which postoperative recovery indicators were monitored.

Intervention Type
Other

Primary outcome measure
The following primary outcome measures are assessed using data collected in medical records at one timepoint:
1. Postoperative hospital stay duration measured in days
2. Time to first mobilization measured in hours
3. Postoperative pain scores measured using the Visual Analog Scale (VAS)
4. Postoperative complication rates e.g., infections, adhesions, or other surgical complications

Secondary outcome measures
The following secondary outcome measures are assessed using data collected in medical records at one timepoint:
1. Changes in Blood Biochemical Markers:
1.1. Preoperative and postoperative hemoglobin levels
1.2. White blood cell counts
1.3. Neutrophil ratio
1.4. C-reactive protein (CRP)
2. Intraoperative Metrics:
2.1. Intraoperative blood loss
2.2. The number of fibroids removed
3. Specific Recovery Milestones:
3.1. Time to first flatus (measured in hours)

Overall study start date
01/01/2018

Completion date
20/06/2022

Eligibility

Key inclusion criteria
1. Patients diagnosed with cervical fibroids by ultrasound, with a fibroid diameter of ≥8 cm
2. Age between 18 and 65 years
3. Availability of complete clinical data, including detailed preoperative examination results

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
300

Total final enrolment
152

Key exclusion criteria
1.Presence of severe comorbidities, such as uncontrolled diabetes or severe cardiovascular or pulmonary diseases.
2.Patients who are pregnant or breastfeeding.
3.History of malignant uterine tumors.
4.Incomplete clinical data or missing preoperative examination results.

Date of first enrolment
31/01/2018

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
China

Study participating centre
Women's Hospital School of Medicine Zhejiang University
No.1 Bachelor Road, Shangcheng District
Hangzhou
China
310000

Sponsor information

Organisation
Science and Technology Department of Zhejiang Province

Sponsor details
33 Huancheng West Road, Xihu District
Hangzhou
China
310000
+86-0571-86964972
jgdw.kjt@zj.gov.cn

Sponsor type
Government

Website
https://www.zj.gov.cn/

ROR
https://ror.org/05yj3y977

Funder(s)

Funder type
Government

Funder Name
Natural Science Foundation of Zhejiang Province

Alternative Name(s)
Zhejiang Natural Science Foundation, , , Zhejiang Provincial Natural Science Foundation, Zhejiang Provincial Natural Science Fund, ZJNSF

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal (BMC Women's Health)

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date