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Application of chain body temperature management checklist in robotic surgery for urology

Submission date
15/10/2024

Recruitment status
No longer recruiting

Registration date
06/11/2024

Overall study status
Completed

Last Edited
30/01/2026

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
To explore the management effect of a chain temperature management checklist in preventing hypothermia during the perioperative period in urological robotic surgery patients.

Who can participate?
Patients aged between 18 and 80 years old undergoing robotic surgery in urology

What does the study involve?
Patients assigned to the control group will be given routine hypothermia protection measures and patients assigned to the intervention group will be managed using a chain temperature management checklist to compare the incidence of hypothermia and chills between the two groups of patients. The incidence of hypothermia and chills, missed implementation of measures, thermal comfort scores, and nurse satisfaction scores will be investigated.

What are the possible benefits and risks of participating?
The benefits include reducing the incidence of low body temperature and shivering, decreasing the rate of implementation omissions and improving patient thermal comfort and nurse satisfaction.

Participation in this study is considered very low risk, as all procedures follow well-established standard processes.

Where is the study run from?
Shanxi Bethune Hospital, China

When is the study starting and how long is it expected to run for?
February 2021 to October 2022

Who is funding the study?
Shanxi Bethune Hospital Hospital-Level Nursing Research Fund

Who is the main contact?
Dr Xiu-Mei Wang, wang3v4xiu9_mei0o@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Application of chain body temperature management checklist

Study objectives
The use of a chain temperature management checklist in the temperature management of patients undergoing urological robotic surgery can reduce the incidence of low body temperature and shivering, decrease the rate of implementation omissions, and improve patient thermal comfort and nurse satisfaction.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/02/2021, Shanxi Bethune Hospital Medical Ethics Committee (No.99 Longcheng Street, Taiyuan, 030032, China; +86-0351-8368114; sxbqeyyrsc@163.com), ref: YXLL-2024-044

Study design

Single center randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Patients undergoing robotic surgery in urology

Interventions
This randomised controlled trial was performed on 152 patients undergoing urological robotic surgery, from March to September 2021, and again from March to September 2022, due to the COVID-19 pandemic. All patients were randomly divided into two groups using computer-generated random numbers.

Set up a perioperative hypothermia prevention and management team: There were 10 team members, including one head of the Department of Anesthesiology and one head nurse of the operating room, who acted as the project team leader, responsible for coordination and scheduling of the overall design, organizational training, and project implementation management of this study; one urologist, anesthesiologist, head nurse of the anesthesiology department, and one head nurse of the ward each to guide the research design and supervise the project implementation process; one operating room robotics specialist team leader to participate in the formulation of the checklist and implementation details and quality control of the project implementation details; two operating room nurses are responsible for document retrieval, inventory preparation, and data collection and analysis.

Formulate a list of perioperative temperature management: Group members search for literature. PubMed, MEDLINE, Web of Science, China National Knowledge Infrastructure (CNKI), Wanfang Database, China Biomedical Literature Database, etc. were searched systematically to select relevant literature as reference materials for low body temperature, robots, urological surgery, low body temperature, and perioperative-related keywords in both Chinese and English. Relevant guidelines and expert consensus, such as 'Expert Consensus on the Prevention and Treatment of Low Body Temperature in Perioperative Patients (2017), Operating Room Nursing Practice Guidelines (2022), ERAS China Expert Consensus and Pathway Management Guidelines (2018): Radical Prostatectomy Section, were consulted. Combined with the actual situation of urological robot surgery and temperature management in our operating room, a systematic understanding and summary of the current status and intervention measures of temperature protection for robot surgery patients at home and abroad were obtained. Based on this, an initial version of the standardized management plan for perioperative chain urological robot sub-speciality temperature protection was formed. After discussion and modification in group meetings, the final draft was transformed into a checklist for temperature management of urological robot surgery patients.

Determination of the perioperative temperature management checklist: Six experts with senior professional titles from Shanxi Province were invited to review the checklist items, including two chief nurses from the operating room, two chief nurses from nursing management, one chief physician from urology, and one from anesthesia. The initial version of the checklist was emailed to the experts, and all six experts provided modification suggestions. The checklist management team summarized and discussed the suggestions, and adjusted and improved the checklist

according to the expert opinions. The final version of the Checklist for Low Body Temperature Management in Urological Robot Surgery Patients under General Anesthesia was formed, including 27 items in four areas: preoperative waiting area, operating room, anesthesia recovery room, and postoperative ward, as well as three links: preoperative waiting area-operating room, operating room-anesthesia recovery room, and anesthesia recovery room-postoperative ward.

Training on the perioperative hypothermia management checklist: Five days before the implementation of the perioperative hypothermia management checklist, the head nurse of the operating room and the leader of the robotic speciality group will provide training to all operating room nurses on the content and key points related to the operating room in the checklist. The head nurse of the anesthesia department will provide training to the anesthesia department nurses on the content related to the anesthesia recovery room in the checklist. The head nurse of the ward will provide training to the nurses on the content related to the postoperative ward in the checklist. All nurses are required to be familiar with, understand, and master the checklist. The nurses in the robotic speciality group will receive focused training (practical exercises) and assessment, and a score of 95 or above is required to pass.

Application of the perioperative hypothermia management checklist: When the patient enters the preoperative waiting area, the internal nurse will implement warming measures for the patient according to the checklist, and check 'Implemented,' 'Not Implemented,' or 'Not Applicable' in the checklist execution column based on the actual implementation. After completing all measures, the nurse will sign and confirm. When the patient enters the operating room, the circulating nurse will implement various warming measures for the patient according to the checklist, and check 'Implemented,' 'Not Implemented,' or 'Not Applicable' in the checklist execution column based on the actual situation. After completing all measures, the circulating nurse will sign and confirm. After the patient arrives at the anesthesia recovery room, the anesthesia nurse once again implements various insulation measures on the patient according to the contents of the list, and checks “implemented”, “not implemented” and “not involved” in the execution column of the list. After all measures have been implemented, they sign and confirm. When the patient returns to the ward after surgery, all insulation measures are completed according to the contents of the list while handing over the patient, and the ward nurse signs and confirms. The transferring party completes insulation measures according to the contents of the list and signs and confirms every step of the transportation. After the contents of the 4-zone 3-link list are filled in, they are kept in the operation archive.

Quality Control: The perioperative hypothermia management checklist is reviewed daily by the head nurse of the operating room to ensure the implementation of the checklist measures in the surgical area. The checklist execution is also reviewed by the head nurse of the anesthesia department to ensure the implementation of the checklist measures in the anesthesia recovery room area. The head nurse of the ward reviews the checklist measures to ensure their implementation in the ward and checks the execution of the checklist. The head nurse of the operating room conducts periodic spot checks. If any problems are found, on-site guidance for improvement is provided. Two months after the implementation of the checklist, the head nurse of the operating room holds weekly meetings with the management team members to analyze the non-executed items and the reasons for non-execution. Improvement suggestions are proposed for continuous quality improvement. In the later stage, the management of the hypothermia checklist will be included in the department's monthly quality control meeting for routine management.

Intervention Type

Procedure/Surgery

Primary outcome(s)
Statistical evaluation of the occurrence of hypothermia in patients measured using data recorded in medical notes from the preoperative waiting area to the postoperative return to the ward

Key secondary outcome(s))
1. Hypothermia incidence rate measured using real-time temperature monitoring conducted on patients. When the patient's core temperature is <36, hypothermia occurs. The hypothermia incidence rate is calculated as (number of hypothermia cases/total number of cases) x 100%. Continuous temperature monitoring was performed between the preoperative waiting area and the postoperative return to the ward
2. The shivering incidence rate is measured using the shivering scale to assess whether the patient experiences shivering each time the area changes. A score of 0 on the scale represents no shivering, a score of 1 represents mild shivering (slight muscle tremors in the face and neck), a score of 2 represents moderate shivering (tremors in one muscle group or limbs), and a score of 3 represents severe shivering (tremors in the whole body). Scores of 1-3 indicate the occurrence of shivering. Shivering incidence = (number of shivering cases / total cases) x 100%
3. The rate of missed implementation of temperature protection measures measured using recorded data: Rate of missed implementation of temperature protection measures = (number of missed implementation cases / total cases) × 100%. Monitored after each application of temperature protection measures
4. Thermal comfort measured by nurses using a Visual Analog Scale (VAS) each time the area is changed, with scores ranging from 0 to 10. The higher the score, the better the comfort.

Completion date
30/10/2022

Eligibility

Key inclusion criteria
1. Patients undergoing robotic surgery in urology
2. American Association of Anesthesiologists (ASA) condition grade I to III
3. Surgery time 2 to 7 hours
4. All methods of anesthesia were general anesthesia
5. 18 to 80 years old, able to communicate effectively
6. Knew about this study and agreed to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit

80 years

Sex
All

Total final enrolment
152

Key exclusion criteria
1. Previous history of severe organ dysfunction or mental illness
2. Previous history of hypothermia or recent history of fever or infection
3. Abnormal blood clotting function, abnormal liver and kidney function, allergy to narcotics, and history of long-term alcohol consumption or opioid abuse
4. Transfer to ICU because of a critical condition after surgery
5. Inability to provide informed consent
6. Any contraindications to the use of the hypothermia management checklist
7. Patients who had undergone surgery within the previous month

Date of first enrolment
01/03/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
China

Study participating centre
Shanxi Bethune Hospital
No.99 Longcheng Street
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Sponsor information

Organisation
Shanxi Bethune Hospital

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Shanxi Bethune Hospital Hospital-Level Nursing Research Fund

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Dr Xiu-Mei Wang, wang3v4xiu9_mei0o@163.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/03/2025	30/01/2026	Yes	No