

# INPLASY PROTOCOL

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**Conflicts of interest:**  
None.

## Operative and oncological outcomes comparing sentinel node mapping and lymphadenectomy in endometrial cancer staging: Meta-Analysis with Trial Sequential Analysis

Gu, Y<sup>1</sup>; Cheng, H<sup>2</sup>; Xiang, Y<sup>3</sup>.

**Review question / Objective:** Current guidelines for endometrial cancer surgical staging including two methods of lymph assessment: sentinel node mapping and lymphadenectomy. Yet the optimal choice for patients remains controversial for blurry benefit of sentinel node mapping. Previous studies have proved the efficiency of sentinel node mapping, and multiple researches, comparing sentinel node mapping and lymphadenectomy, has been published recently. Hither to, a systematic review and meta-analysis to identify current high-quality evidences, including operative and oncologic outcomes, is needed.

**Condition being studied:** Endometrial cancer (EC) is one of the common gynecological malignancies, especially in woman aged 55-60 years. The new case of EC can rise to 65000 every year, and EC rank first in the list of 2020 United States women cancer statistics. Albeit early-stage EC patients has a good prognosis, with a high 5-year survival rate of 90%, recurrent and metastatic EC patients often struggle to reach a 16% 5-year survival rate. Lymph node status is the most significant predictor of survival, and guides postoperative treatment decision making in EC patients. The two current node assessment methods, sentinel node mapping and lymphadenectomy, are been widely performed at the practitioner's discretion. There are growing evidences showing the safety and efficacy of sentinel node mapping, especially in low-risk EC patients. Several recent publications indicated sentinel node mapping was superior to lymphadenectomy in perioperative outcomes and nodal assessment. Albeit previous analyses have compared the two methods, some aspects like operative outcomes, and oncologic outcomes still remain discussion.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 April 2020 and was last updated on 13 April 2020 (registration number INPLASY202040071).

### INTRODUCTION

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staging including two methods of lymph assessment: sentinel node mapping and lymphadenectomy. Yet the optimal choice for patients remains controversial for blurry

benefit of sentinel node mapping. Previous studies have proved the efficiency of sentinel node mapping, and multiple researches, comparing sentinel node mapping and lymphadenectomy, has been published recently. Hither to, a systematic review and meta-analysis to identify current high-quality evidences, including operative and oncologic outcomes, is needed.

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## METHODS

**Search strategy:** The key words included "Endometrial cancer", "cancer of corpus uteri", "uterine corpus cancer", "uterine cancer", "sentinel node mapping" and "lymphadenectomy".

**Participant or population:** Endometrial cancer patients.

**Intervention:** Sentinel node mapping(SLN) is an approach to evaluate lymph nodes by

injecting markers like indocyanine green, and by targeting primary nodes that drain a malignancy, gynecological oncologist can better identify positive nodes.

**Comparator:** Lymphadenectomy(LND) means pelvic and/or para-aortic lymph node dissection up to the renal vessel. In this group, patients who underwent sentinel node mapping will be excluded.

**Study designs to be included:** Random controlled trials, cohort studies.

**Eligibility criteria:** Studies were included if they met the following criteria: 1) patients diagnosed with endometrial cancer; 2) clinical trials concerning the comparison of sentinel node mapping and lymphadenectomy; 3) reported operative outcomes like operative time, blood loss, operative complications; lymph nodes assessment like the number of positive pelvic lymph nodes; oncological outcomes like overall survival and recurrence, but not limited to these above. The exclusion criteria as: 1) <10 patients; 2) review, case report, comment, and other types without original data; 3) full text could not be obtained; 4) written other than in English.

**Information sources:** A comprehensive and systematic search was conducted in MEDLINE, EMBASE, Cochrane library, Web of science, Ovid databases from earliest inception to April 2020 respectively. Registered clinical trials on [ClinicalTrials.com](https://www.clinicaltrials.com), Controlled Trials meta Register and WHO were searched as well.

**Main outcome(s):** Operative outcomes like operation time, blood loss complications; lymph node assessment results like positive node rate; oncological outcomes like survival rate, PFS.

**Additional outcome(s):** None.

**Quality assessment / Risk of bias analysis:** Two independent reviewers will assess the quality of including studies. Cochrane Collaboration's Risk of Bias assessment tool will be used to assess the quality of RCT, and Newcastle Ottawa scale will be

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used to assess the quality of no-RCT. Other types of trails will be assessed using Cochrane-recommended tools. The methods, baseline balances, outcome recording and blinding will be assessed.

**Strategy of data synthesis:** All the available data will be recorded in a summary excel table. Then we will screen the table to sort identical items together. If data cannot be compared, a narrative synthesis will be conducted. Data will be added into Review manager 5.3 for a meta-analysis. Der-Simonian and Laird random-effects models will be used to pool log transformed event rates and estimated 95% CI for dichotomous outcomes, and for continuous outcomes, we will calculate the weighted mean difference (MD) between sentinel node mapping and lymphadenectomy for each study and we will pool the effect size using the same models. Across the included studies will measure the overall heterogeneity using  $I^2$  statistic, in which  $I^2 > 50\%$  suggests high heterogeneity. To identify the reason of high heterogeneity, subgroup analysis will be conducted. Trial sequential analysis will be performed.

**Subgroup analysis:** Subgroup analysis by SLN procedure or patients risk stratification will be introduced.

**Sensibility analysis:** Sensibility analysis will be conducted when meeting high heterogeneity.

**Country(ies) involved:** China.

**Keywords:** Endometrial cancer; sentinel node mapping; lymphadenectomy.

**Contributions of each author:**

Author 1 - Conceptualization, methodology, writing the manuscript.

Author 2 - Methodology.

Author 3 - Project administration.