SFOG-veckan i Örebro 2 -5 september 2024

Opportunistisk salpingektomi

Annika Strandell

Opportunistisk salpingektomi för prevention av ovarialcancer

Annika Strandell

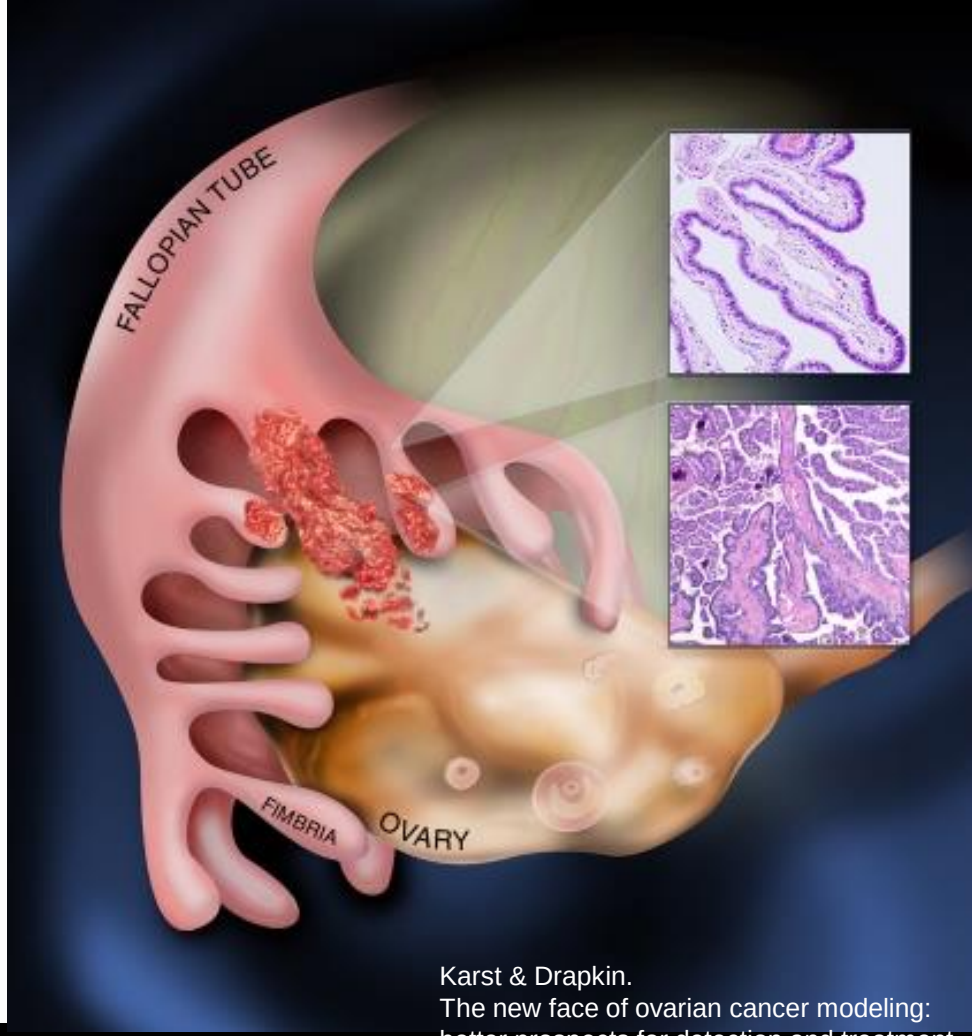
Principal investigator

Inga intressekonflikter att redovisa

Bakgrund till opportunistisk salpingektomi

- Modell enligt Shih & Kurman (2004)
- High grade serous ovarian cancer
- STIC

  Serous Tubal Intraepithelial Carcinoma



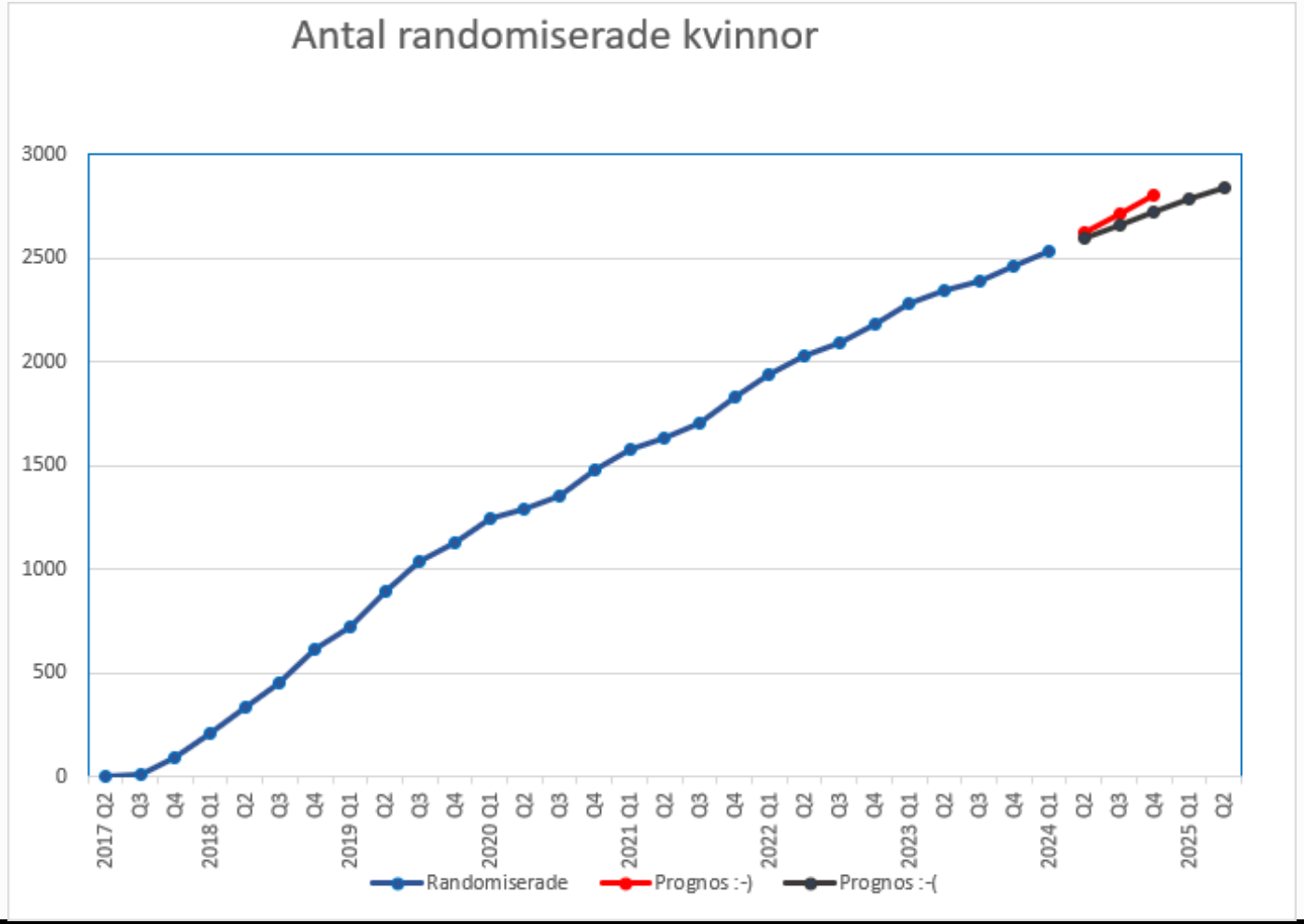
Karst & Drapkin.
The new face of ovarian cancer modeling: better prospects for detection and treatment. *F1000 Med Rep*. 2011.

Evidensläget för opportunistisk salpingektomi

Fortfarande kunskapsluckor avseende

- Komplikationer
- Ovarialfunktion / menopausrelaterade symptom
- Effektens storlek på minskad incidens ovarialcancer

HOPPSA


Antal randomiserade kvinnor
3000
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Q4
2025 Q1
Q2
Randomiserade
Prognos :-)
Prognos :-(

Medförfattare

GÖTEBORGS UNIVERSITET

Leonidas Magarakis
Karin Sundfeldt
Mathias Pålsson

UMEÅ UNIVERSITET

Annika Idahl
Per Liv

Övergripande syfte

Studera säkerheten vid laparoskopisk salpingektomi

för sterilisering jämfört med tubarligering

Primära utfallsmått

- Komplikationer upp till åtta veckor postoperativt

- Ålder vid naturlig menopaus

  -som ett mått på ovarialfunktion

Design

- Nationell, multicenter (41 centra)
- Register baserad RCT
- Non-inferiority design
- Sample size 968 women

Primary outcome Complications
Statistics

- Primary analysis based on the per-protocol population (non-inferiority)
  - Multiple imputation

- Generalised estimation equation (GEE)

  -with logistic link function

  -marginalised over centre

  to estimate the difference in complication risk between groups.

Sekundära utfallsmått

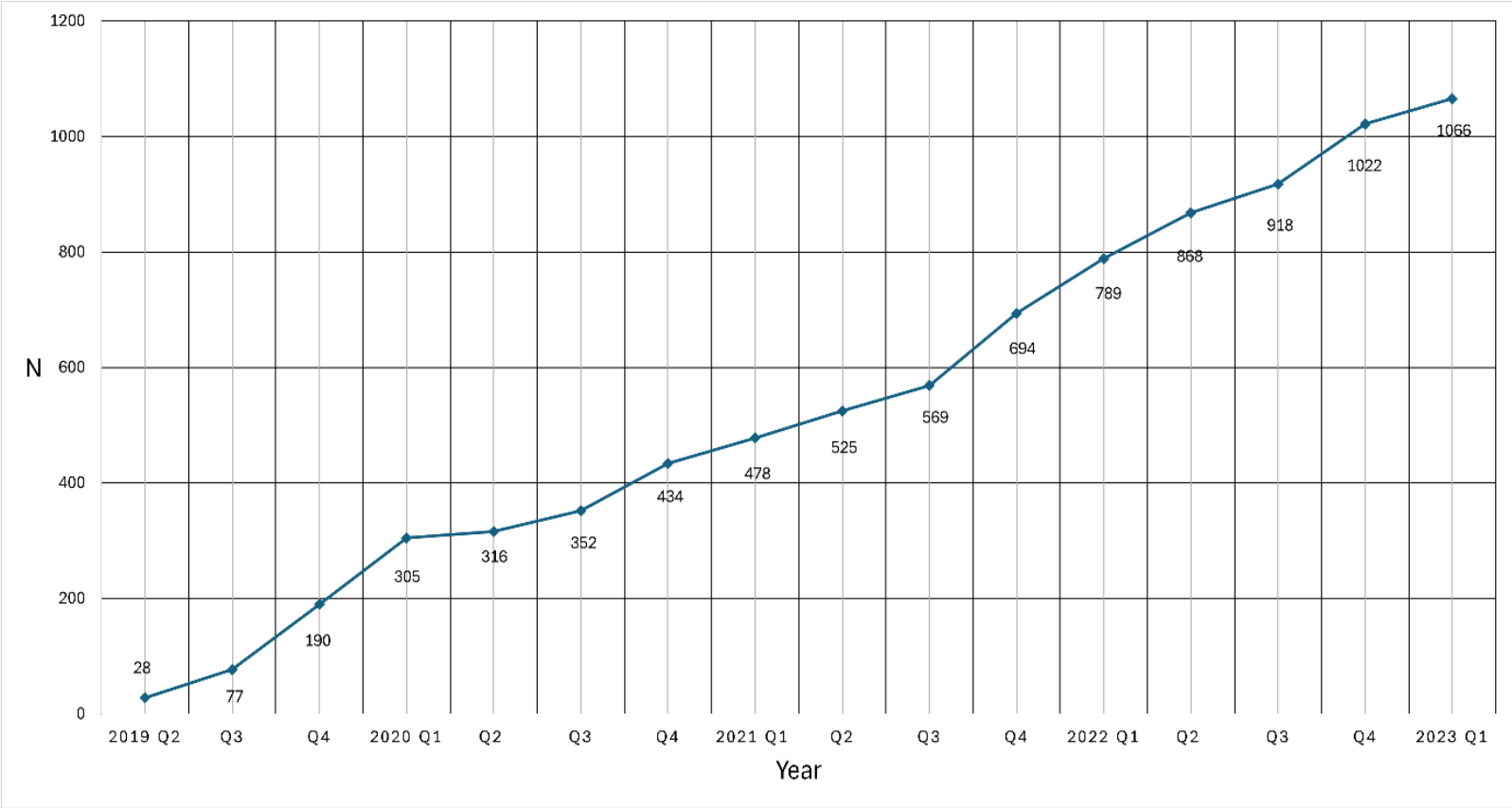
- Operationstid
- Intraoperativ blödning
- Allvarlig komplikation
- Lätt komplikation
- Klassificering enligt Clavien-Dindo

Participants

- Inclusion criteria
- Women under the age of 50
- Planned for laparoscopic sterilisation

- Exclusion criteria
- Previous malignancy involving radiation, chemotherapy or endocrine treatment affecting ovarian function.
- Non-understanding of the study information available in Swedish.

SALSTER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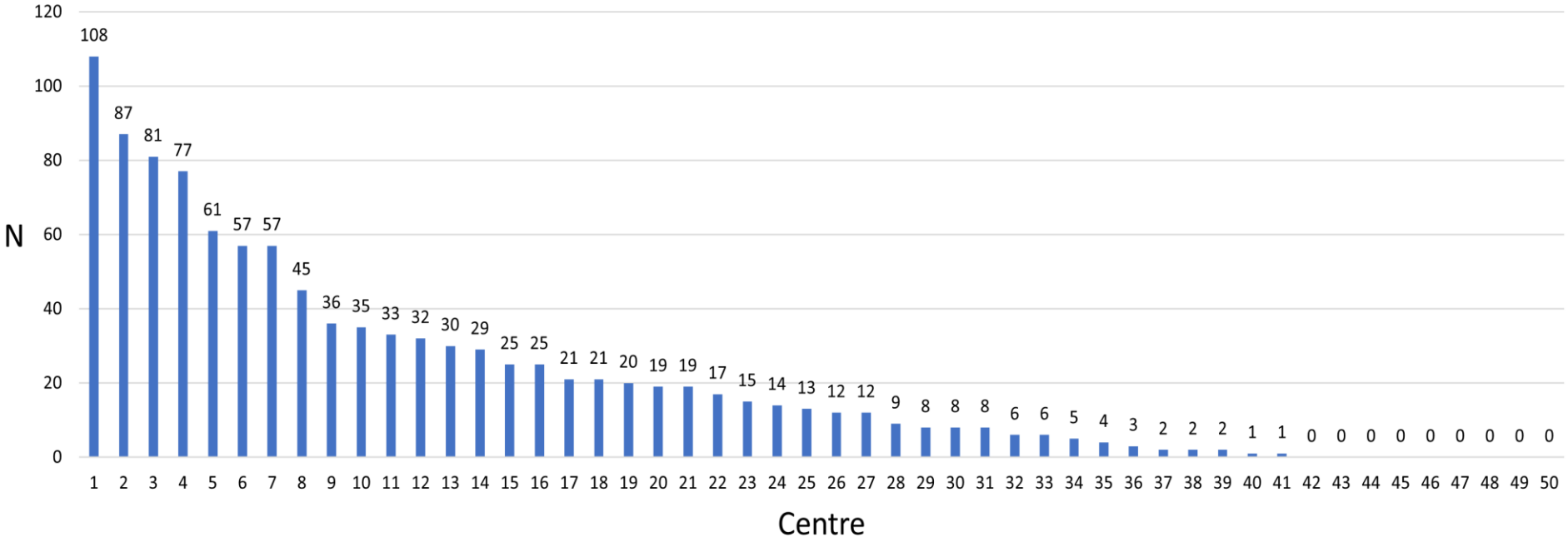
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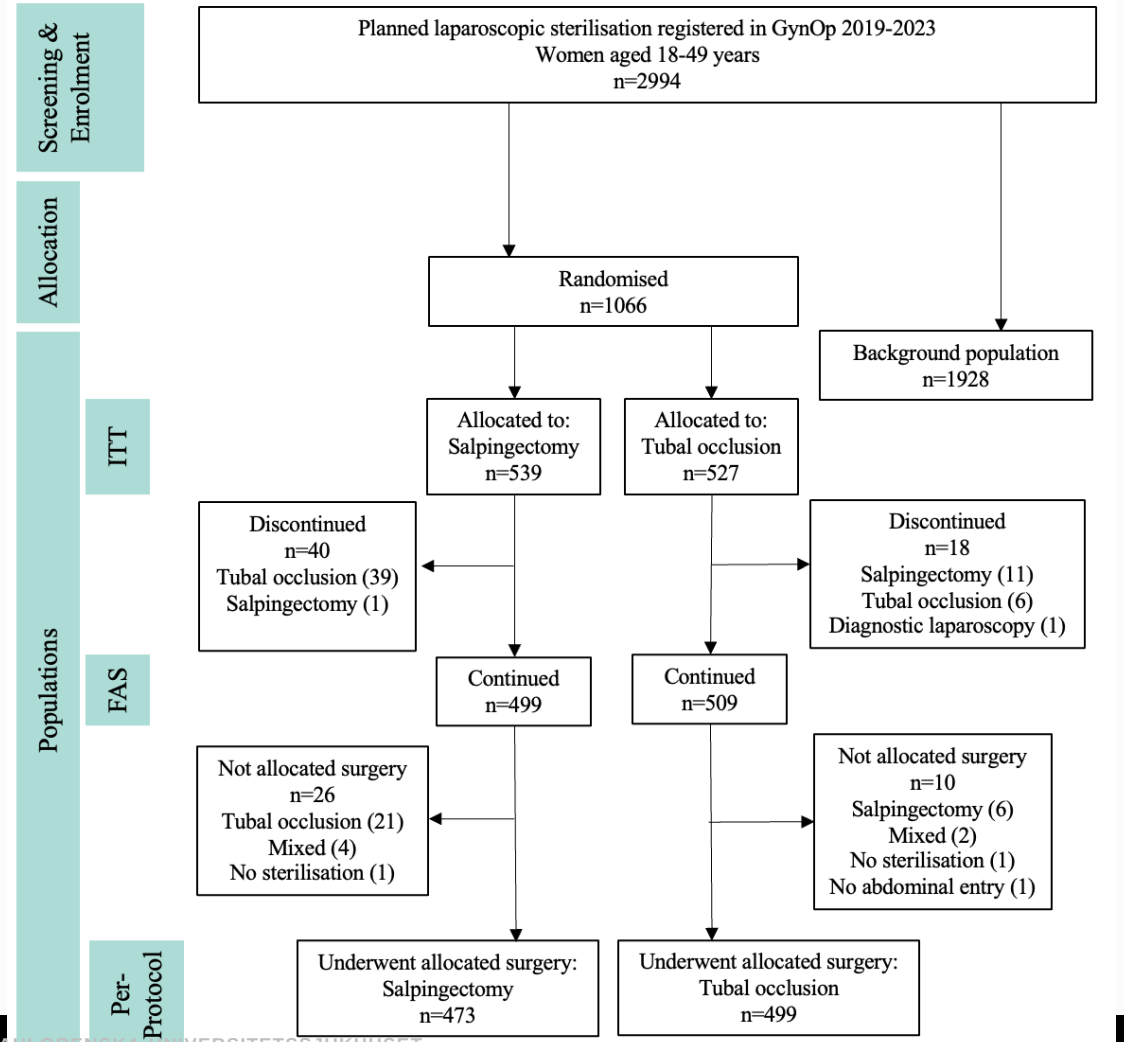
Centre

SALSTER

ITT: Intention-To-Treat

FAS: Full-Analysis-Set



Baseline characteristics of the randomisation groups

Characteristics	Salpingectomy n= 539	Tubal occlusion n=527
Age (years)	36.2 (5.0)	36.0 (5.4)
BMI (kg/m^2)	26.7 (5.2)	26.8 (5.2)
Smokers	14%	17%
ASA I-II	99%	99%
Prior abdominopelvic surgery	32%	32%
Prior *C. trachomatis* infection	29%	27%
Mental condition	23%	20%

Primary outcome - Any complication

	Salpingectomy n=473	Tubal occlusion n=499	p value
Any complication	38.5 (8.1%)	31.0 (6.2%)	0.26

Difference: 1.9 pp, 95% CI (-1.4 to 5.3)

Secondary outcome - Severe complications

	Salpingectomy n=473	Tubal occlusion n=499
Severe complication	1 (0.2%)	1 (0.2%)

Secondary outcome - Complications classified according to Clavien-Dindo

	Salpingectomy n=473	Tubal occlusion n=499
1	30.2 (6.4%)	23·6 (4.7%)
2	6.3 (1.3%)	6.3 (1.3%)
3a	1.0 (0.2%)	0.1 (<0.1%)
3b	1.0 (0.2%)	1.0 (0.2%)

Operative time (min)

	Salpingectomy n=501	Tubal occlusion n=509
Mean (SD)	44.4 (18.5)	29.7 (15.9)
Median [Q1-Q3]	42 [30-55]	26 [19-37]

Difference: 15.6 min, 95% CI (12.6-16.9)

p<0.001, two-sided t-test

Perioperative bleeding (ml)

	Salpingectomy n=501	Tubal occlusion n=508
Mean (SD)	6.7 (11.2)	4.1 (9.4)
Median [Q1-Q3]	5 [0-10]	0 [0-5]

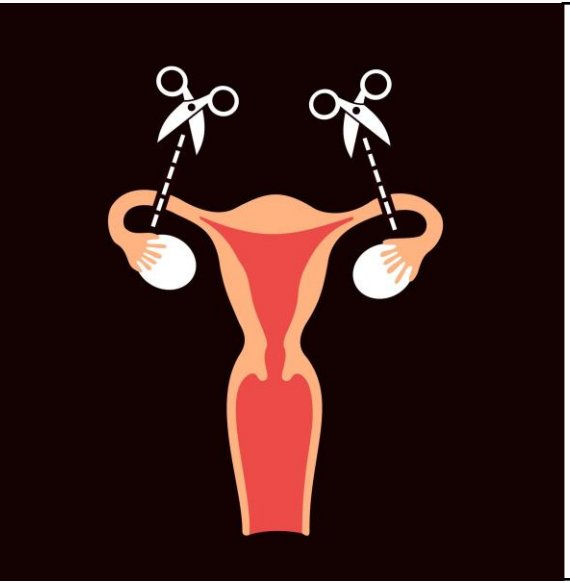
Difference: 2.6 ml

OR 2.33, (95% CI 1.8-3.0), p<0.0001

Instrument choice for *salpingectomy*

	n	%
Bipolar energy	271	54
Advanced bipolar device	222	44
Cold scissors	122	24
Monopolar energy	38	8
Compination of ultrasonic and advanced bipolar device	10	2
Ultrasonic device	4	0.8
Other	4	0.8

Surgical technique for *tubal occlusion*



	n	%
Coagulation and division	486	95.4
Application of ring, clips etc	10	2.2
Other method	1	0.2
Missing	10	2.2
Total	509	100

- Complications up to 8 weeks post-op

- Overall complication rate

SALSTER
(ITT)

85/1066
8.0 %

Background population

101/1488
6.8 %

Slutsats

Laparoskopisk salpingektomi vid sterilisering

orsakade inte fler komplikationer

upp till 8 veckor postoperativt

(enligt fördefinierad gräns för non-inferiority)

än tubarligering

Ytterligare slutsatser

- Operationstid

16 min längre för salpingektomi än tubarligering

- Perioperativ blödning

Signifikant större för salpingektomi men utan klinisk relevans

Kliniska implikationer

- Viktig information till kvinnor innan sterilisering
- Möjliggör beslut i samråd

- Påverkan på ovarialfunktion och menopaus kommer redovisas av SALSTER

- Okänt hur mycket opportunistisk salpingektomi minskar ovarial cancer incidens

Salpingectomy versus tubal occlusion in laparoscopic sterilisation (SALSTER): a national register-based randomised non-inferiority trial

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Summary

Background Opportunistic salpingectomy to reduce ovarian cancer incidence has become increasingly common despite the lack of randomised trials investigating its safety. In SALSTER, we tested whether salpingectomy for laparoscopic sterilisation is non-inferior to tubal occlusion regarding complications up to eight weeks postoperatively.

Methods SALSTER is a register-based randomised non-inferiority trial in which 41 gynaecological departments in Sweden participated. After being reported to The Swedish National Quality Register of Gynaecological Surgery (GynOp) for laparoscopic sterilisation, women aged <50 years received study information and could consent to participation online. If eligible, randomisation was performed by the examining/operating gynaecologist before surgery, with stratification for centre, and allocation 1:1 to salpingectomy or tubal occlusion. Blinding was attempted for patients but was impossible for surgeons. The first primary outcome, any complication up to eight weeks postoperatively, was routinely reported in GynOp through physician assessment of patient questionnaires, medical records and personal contact. Complications up to eight weeks postoperatively, a primary safety outcome, were analysed in the per-protocol population. The non-inferiority margin for the difference in the absolute risk of complications was defined as ten percentage points. Missing data were handled using multiple imputation. SALSTER was registered at ClinicalTrials.gov (NCT03860805).

Findings Between April 4, 2019, and March 31, 2023, 539 women were randomised to salpingectomy and 527 to tubal occlusion. In the salpingectomy and tubal occlusion arms, 40 and 18 women discontinued their participation in the trial and another 26 and 10 did not receive the allocated surgery, respectively. Calculated on imputed data, any complication up to eight weeks postoperatively occurred in 8.1% (38.5/473) of patients after salpingectomy and in 6.2% (31.0/499) of patients after tubal occlusion. The risk difference was 1.9 percentage points (95% confidence interval −1.4 to 5.3).

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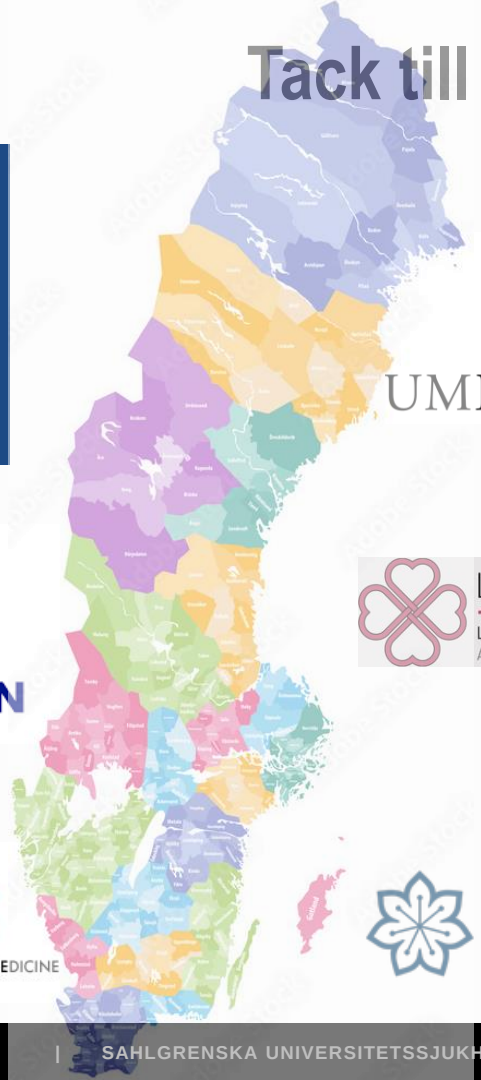
Tack till sponsorer



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