Cover page - statistical analysis plan

Title

Obstetric outcome in pregnancies treated with laparoscopic cerclage: an observational study in a Danish cohort

Roles and Responsibility

Study group
Principal investigator; Lise Qvirin Krogh, MD[1]
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Conflicts of interest

The members of the study group have no conflicts of interest to declare. The study sponsor has no ultimate authority over any aspects of the study design, conduct, or reporting.

Trial registration

The study is registered at clinicaltrials.gov using the administrative authorities of Aarhus University (UAarhus). NCT not yet assigned.

Funding

Funding for the study is provided as a part of a larger grant by the Novo Nordic Foundation.

Statistical analysis plan

Statistics will be descriptive and data will be presented with counts and percentages for categorical variables, mean and standard deviation for continuous Gaussian distributed variables, and median and interquartile range for continuous non-Gaussian variables. Proportions will be presented with a 95% confidence interval for the dichotomous outcomes.

Subgroup analyses of the primary outcome will be undertaken for the following subgroups:

- Prior versus no prior cesarean delivery at time of laparoscopic cerclage
- Prior versus no prior conisation at time of laparoscopic cerclage
- Placement of laparoscopic abdominal cerclage before or during early pregnancy

STATA will be used for data management and analyses.

Examples of anticipated tables is shown below.

Table 1. Maternal Characteristics upon laparoscopic cerclage placement

n	*n*
Age, years	mean (range)
Smoking	no. (%)
Body Mass Index (kg/m^2)	median (interquartile range)
Parity	median (interquartile range)
Previous conization	no. (%)
- 0	no. (%)
- 1 conus	
- 2+	
Previous caesarean delivery	
Performed as emergency caesarean	no. (%)
Previous uterine surgery	no. (%)
Placement of laparoscopic ceclage during pregnancy	no. (%)
Indications for the laparoscopic cerclage placement	
a) Previous emergency/laboring cesarean delivery followed by a spontaneous singleton late miscarriage or preterm birth from 16+0 to 28+0 weeks	no. (%)
b) Previous elective vaginal cerclage placement but nonetheless a spontaneous late miscarriage or preterm birth between 14+0 and 28+0 weeks (= failed vaginal cerclage)	no. (%)
c) Previous ultrasonography-indicated emergency cerclage with preterm birth between 14+0 and 28+0 weeks	no. (%)
d) Conization and a short pre-pregnancy cervix	no. (%)
e) Two or more deliveries in gestational age 16+0 to 28+0 weeks and a clinical diagnosis of cervical insufficiency	no. (%)
f) Three or more deliveries in gestational age 16+0 to 36+6 weeks	no. (%)
g) Others	no. (%)

Table 2. Characteristics laparoscopic cerclage procedure

n	*n*
Additional procedures performed during surgery	no. (%)
Performed in Day Surgery	no. (%)
Year of surgery	
2011 trough 2014	no. (%)
2015 trough 2018	no. (%)
2019 trough 2022	no. (%)
Early complications	
Conversion to laparotomy during surgery	no. (%)
Haemorrhage > 500 ml	no. (%)
Postoperative infection treated at hospital	no. (%)
Damage to internal organs	no. (%)
Need for re-operation	no. (%)
Admission to Intensive Care Unit	no. (%)
Thromboembolic events	no. (%)
Maternal cardiopulmonary arrest	no. (%)
Maternal death	no. (%)
Late complications	
Erosion into the vagina treated in hospital	no. (%)
Pain complaints from the stiches leading to intervention in pregnancy	no. (%)
Other complications from the cerclage leading to intervention in hospital	no. (%)

Table 3. Pregnancy outcomes and neonatal survival subsequent to laparoscopic cerclage placement

Pregnancy no.	n	Neonatal survival	Neonatal survival without major morbidity	Time of miscarriages or delivery						Gestational age
				≤16 GW	≤22 GW	≤28 GW	≤32 GW	≤34 GW	≤37 GW	
1	n	prop. (95% CI)	prop. (95% CI)	no. (%)	no. (%)	no. (%)	no. (%)	no. (%)	no. (%)	median (IQR)
2	n	prop. (95% CI)	prop. (95% CI)	no. (%)	no. (%)	no. (%)	no. (%)	no. (%)	no. (%)	median (IQR)
3	n	prop. (95% CI)	prop. (95% CI)	no. (%)	no. (%)	no. (%)	no. (%)	no. (%)	no. (%)	median (IQR)
4	n	prop. (95% CI)	prop. (95% CI)	no. (%)	no. (%)	no. (%)	no. (%)	no. (%)	no. (%)	median (IQR)
5	n	prop. (95% CI)	prop. (95% CI)	no. (%)	no. (%)	no. (%)	no. (%)	no. (%)	no. (%)	median (IQR)

Table 4. Time intervals

n	*n*
Time from the laparoscopic cerclage to first pregnancy (years and days)	median (IQR)

Table 5. Characteristics of live born neonates

n	*n*
Gestational age at birth	no. (%)
Birth weight (g)	median (IQR)