

Bydgoszcz, dnia 13.06.2024r

Imię i nazwisko: **Wojciech Flis**

Tytuł zawodowy: lekarz

Streszczenie rozprawy doktorskiej w języku angielskim

Autor rozprawy: lek. Wojciech Flis

Tytuł rozprawy: Comparison of the clinical effectiveness of two labor pre-induction and induction regimens using oral prostaglandin E1 analogues and a single-balloon Foley catheter in patients with term pregnancy

Promotor: dr hab. n. med. i n. o zdr. Maciej Władysław Socha, profesor UMK

Dziedzina: Nauki medyczne i nauki o zdrowiu

Dyscyplina: Nauki o zdrowiu

Induction of labor remains one of the most frequently performed obstetric procedures. This procedure involves artificial (iatrogenic) triggering of the contractile activity of the uterine muscle, the main purpose of which is to lead to vaginal delivery within 24-48 hours, before its spontaneous onset.

The aim of the study is to compare the clinical effectiveness of two popular induction and pre-induction of labor regimens using a single-balloon Foley catheter and oral prostaglandin E1 analogues in patients with term pregnancy.

The prospective, randomized, controlled clinical trial included 200 patients with term pregnancy with indications for induction of labor. The patients underwent labor induction at the Obstetrics and Gynecology Department of St. Adalbert's Hospital COPERNICUS Healthcare Entity. Following the 1:1 randomization principle, 100 patients were assigned to the group receiving a Foley catheter as the pre-induction of labor, and 100 patients to the group receiving oral prostaglandin E1 analogues (Mizoprostol) as the pre-induction of labor. The assumption of the clinical procedure was based on the additional supply of oxytocin in patients in whom contractions did not begin approximately 24 hours after the start of labor induction.

Regardless of the method used, a high degree of cervical maturity was achieved in the study groups. The predominant route of delivery was vaginal delivery. There were no differences in the overall rate of cesarean sections and vaginal deliveries depending on the induction of labor protocol used.

Most patients delivered within 48 hours (regardless of the method used). Statistical significance was demonstrated for an overall higher percentage of deliveries within 24 hours, a higher percentage of vaginal deliveries within 24 hours and a higher percentage of cesarean sections within 24 hours after the Mizoprostol administration. In turn, the use of a single-balloon Foley catheter was associated with a significantly higher overall percentage of deliveries within 24-48 hours and with a significantly higher percentage of vaginal deliveries within 24-48 hours. There were no statistically significant differences in the percentages of indications for cesarean section.

Considering specific time intervals, the use of the pre-induction and induction protocol with oral Mizoprostol was associated with a significantly shorter time to the onset of labor and shorter time to the onset of contractions.

It was shown that the use of Mizoprostol was associated with a significantly lower need for oxytocin during labor.

When analyzing the birth condition of newborns, no significant differences were observed in the Apgar scores and umbilical cord blood pH, regardless of the method of pre-induction and induction of labor used.

Based on the study and the results, the following conclusions were drawn:

- Labor induction protocols using mechanical methods (based on a single-balloon Foley catheter) and pharmacological methods (based on oral Misoprostol) show the same clinical effectiveness
- The use of the studied labor induction regimens does not increase the rate of cesarean sections and does not lead to an increase in the rate of cesarean section due to lack of labor progress or due to non-reassuring fetal heart rate patterns.
- The labor induction protocol using pharmacological methods (Misoprostol), compared to the labor induction protocol using a mechanical method (Foley catheter), leads to faster labor and delivery, which is more likely to occur within the first 24 hours (before the definitional criterion of labor induction).

- The labor induction protocol using mechanical methods (Foley catheter) and the protocol based on the pharmacological method (oral Misoprostol) lead to cervical ripening equally effectively.
- The use of the studied labor induction protocols does not increase the rate of operative vaginal deliveries.
- The use of both a Foley catheter and oral Misoprostol in the induction of labor is characterized by a high safety profile.

Wojciech Flis