



# Safety and Efficacy of the Foley Balloon for Cervical Ripening During Induction of Labor in Women with Prior Cesarean

Jessika Ralph, MD, Elizabeth Newman, BS, Liyun Zhang, MS, Pippa Simpson, PhD, Judith Hibbard, MD

Department of OB/GYN, Specialty of Maternal-Fetal Medicine, Medical College of Wisconsin



## ABSTRACT

**Introduction**  
Induction of labor in women with prior cesarean is a safe alternative to repeat cesarean. Current evidence has not determined the best method for women who require cervical ripening. We sought to determine whether the use of the Foley balloon is comparable in safety and efficacy to oxytocin.

**Methods**  
We conducted a retrospective chart review of all women with prior cesarean undergoing induction between 1990 and 2015. We compared the vaginal delivery rate, maternal adverse event composite, and neonatal adverse event composite. The maternal composite included hemorrhage, infection, uterine rupture, and maternal death. The neonatal composite included 5m APGAR < 7, umbilical artery pH < 7, NICU admission, and neonatal death. Confounding variables, including Bishop score, previous vaginal delivery, gestational age, and presence of PROM, were identified by logistic regression.

**Results**  
66 women were induced by Foley balloon and 405 by oxytocin. The vaginal delivery rate was significantly less in the Foley balloon group compared to the oxytocin group (55% vs 75%, p=0.001). The rates of maternal and neonatal adverse events were equivalent (24% vs 15%, p=0.070; 11% vs 10%, p=0.86). Logistic regression determined that women with 3 or more deliveries (odds ratio 0.22 (CI 0.01, 0.05)) and gestational age greater than 36 weeks (OR 0.30 (CI 0.11, 0.80)) were associated with decreased likelihood of maternal adverse events; premature rupture of membranes (OR 3.91 (CI 1.93, 7.92)) was associated with increased likelihood of neonatal adverse events.

**Conclusions**  
With careful patient selection, Foley balloon is an acceptable induction method in women with prior cesarean.

## BACKGROUND

- Trial of labor after cesarean (TOLAC) can be an appropriate alternative to repeat cesarean section
  - Successful vaginal delivery occurs in 75% of TOLAC candidates
  - It is associated with a <1% risk of uterine rupture
- Induction of labor (IOL) with oxytocin in TOLAC candidates increases the risk of uterine rupture to approximately 1%
- Prostaglandins increase the risk of uterine rupture to 2-3%
- In women without a history of cesarean section, the Foley balloon is an alternative method of cervical ripening with comparable rates of successful vaginal delivery

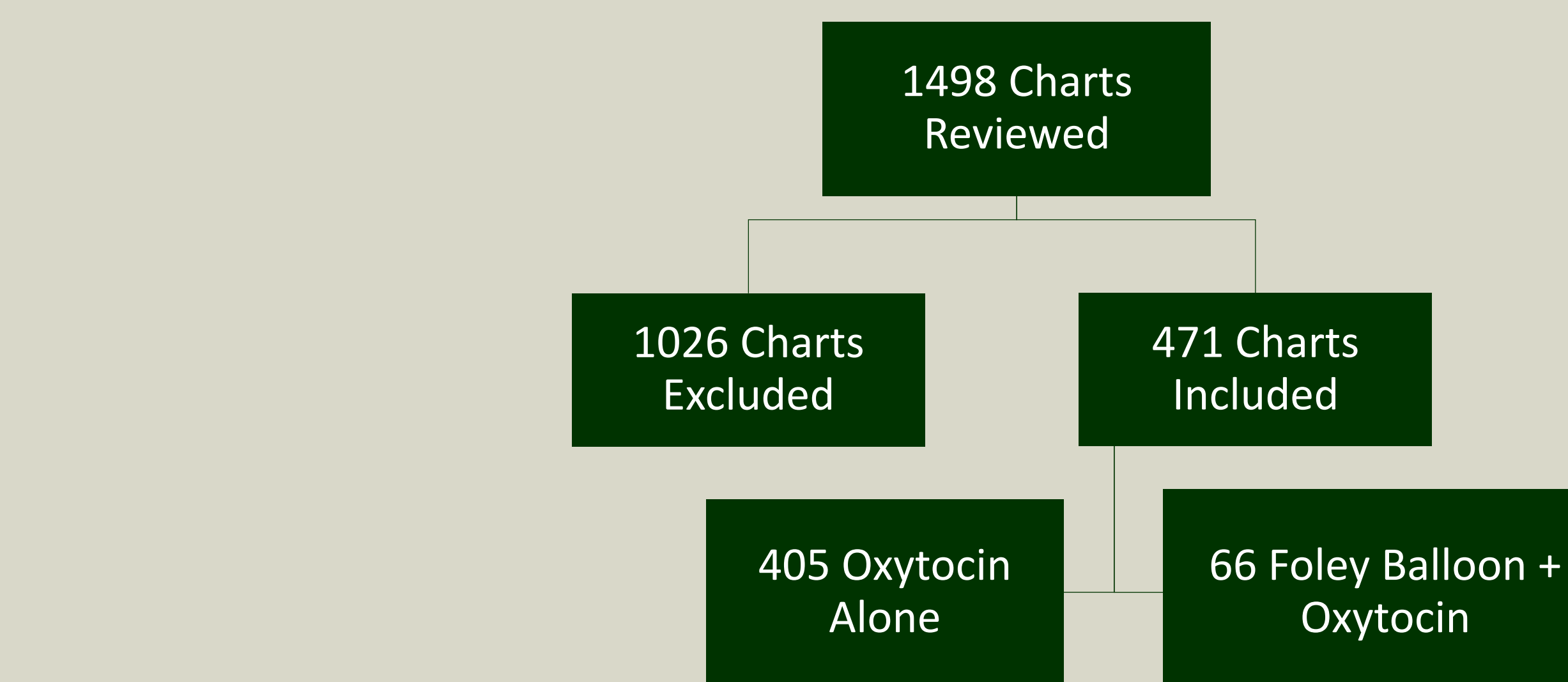
## OBJECTIVE

- To compare for TOLAC candidates undergoing induction of labor with Foley balloon vs oxytocin:
  - Rate of maternal hemorrhage, chorioamnionitis, and uterine rupture
  - Rate of repeat cesarean section
  - Rate of neonatal death and asphyxia

## STUDY DESIGN

- Retrospective chart review at two institutions of women with a history of cesarean section undergoing induction of labor
  - Inclusion criteria: all women with history of cesarean section undergoing induction at Froedtert and CSM between 1994 and 2015
  - Exclusion criteria: women delivering a fetus less than 24 weeks, stillbirth, and fetuses with lethal anomalies
- Chi-square and Fisher’s Exact tests were used to compare categorical variables
- Mann-Whitney test was used to compare continuous variables
- Tree analysis was performed to estimate the impact of demographic information on tested outcomes
- Significant outcomes were defined as p < 0.05

## RESULTS



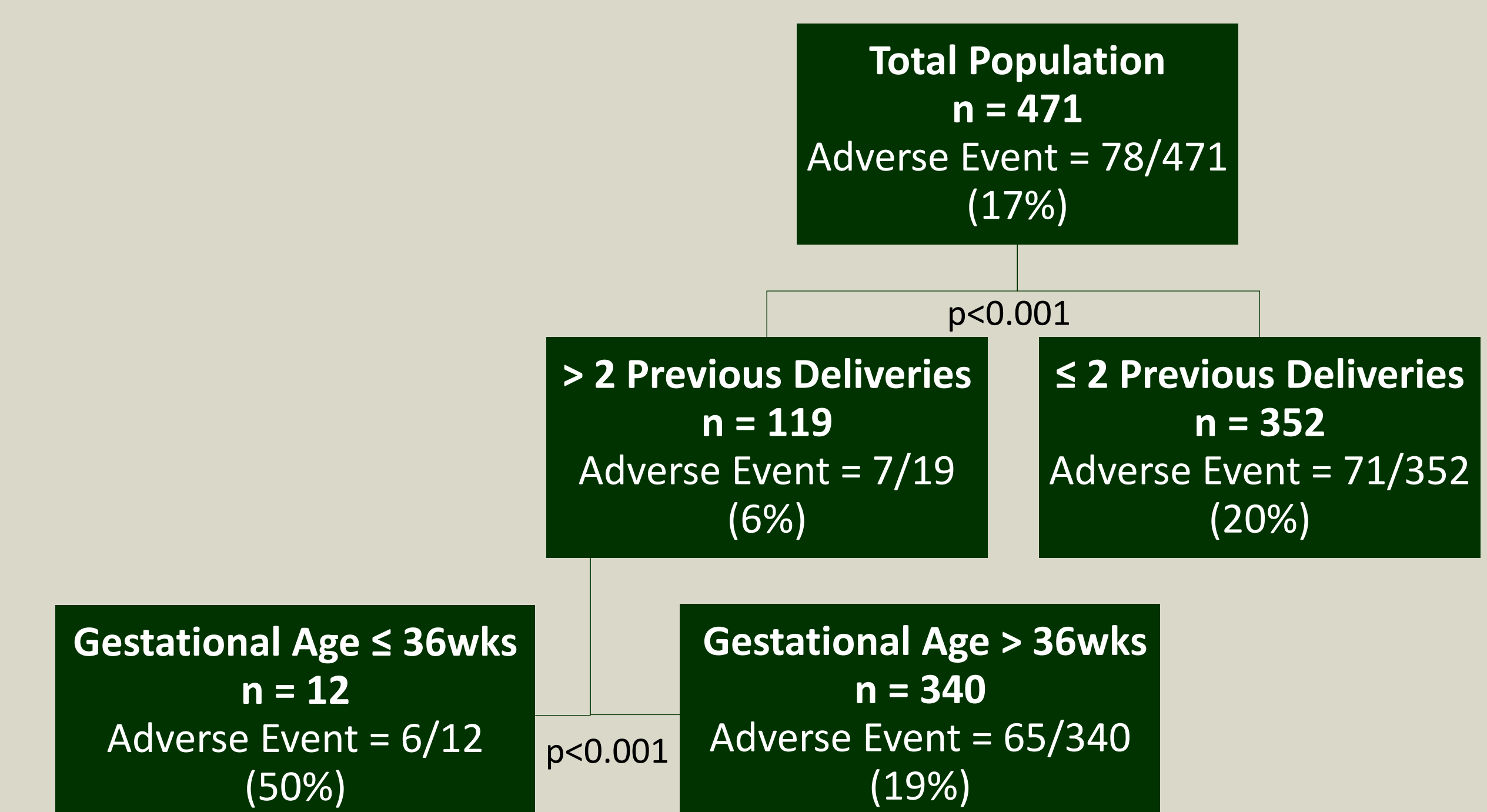
DEMOGRAPHICS			
	Oxytocin n=405	Foley Balloon n=66	p
Maternal Age (years, median (range))	30 (18, 51)	30 (21, 44)	0.54
Race (n)			
White	163 (40.3%)	31 (47.0%)	0.63
Black	112 (27.7%)	17 (25.8%)	
Hispanic	92 (22.7%)	11 (16.7%)	
Maternal Hypertensive Disease (n)	32 (7.9%)	16 (24.2%)	< 0.0001
Maternal Diabetes (n)	44 (10.9%)	10 (15.2%)	0.31
PROM (n)	53 (13.1%)	2 (3%)	0.1
Cervical Exam (cm, median (range))	3.0 (0.0, 10.0)	1.0 (0.0, 4.0)	< 0.0001
Gestational Age (weeks, median (range))	39.3 (25.6, 41.4)	39.2 (33.0, 41.6)	0.64
Birth Weight (g, median (range))	3290 (880, 5140)	3290 (1890, 4309)	0.39

## RESULTS

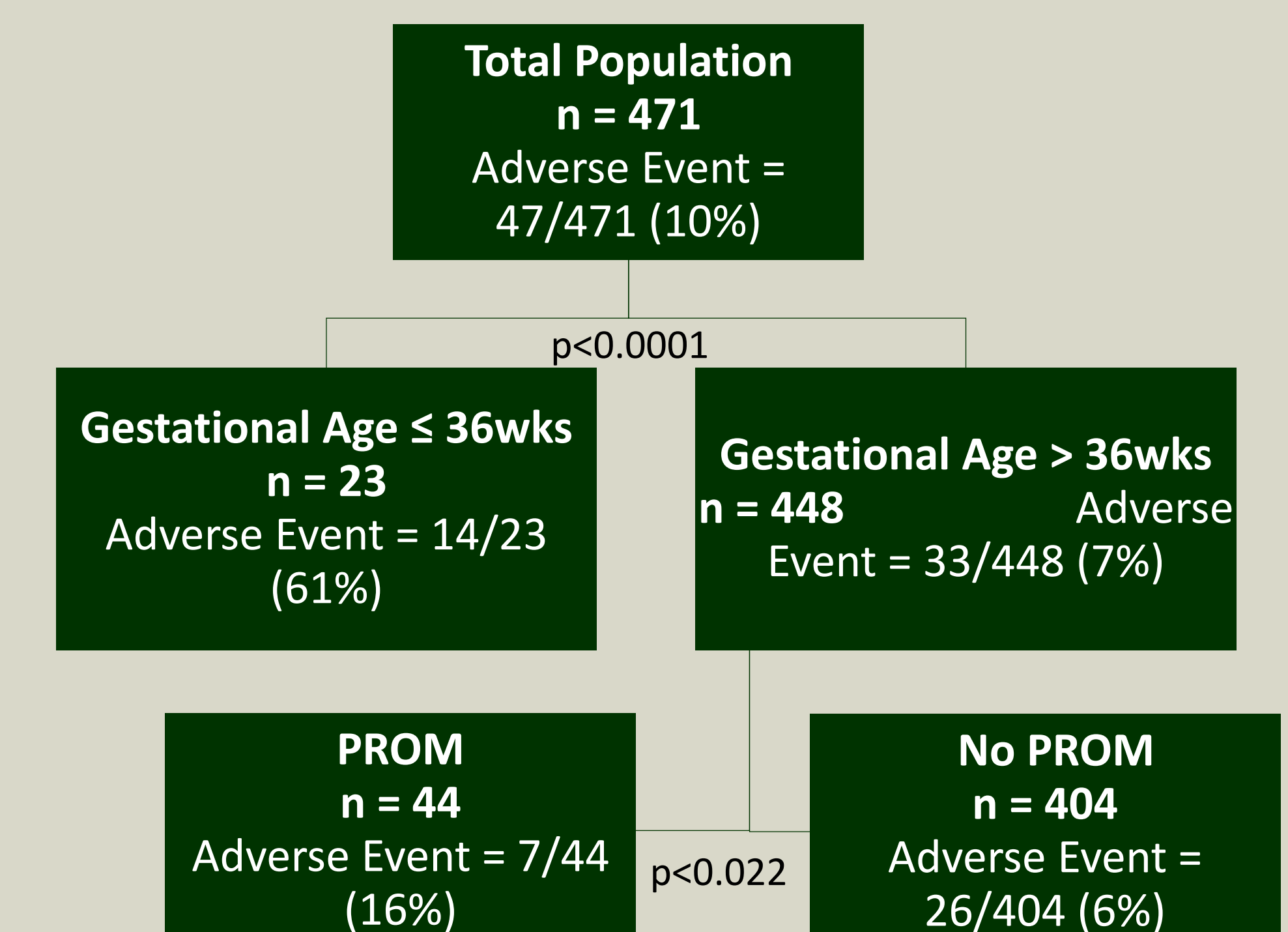
DELIVERY OUTCOMES			
	Oxytocin n=405	Foley Balloon n=66	p
Labor Length (minutes, median (range))	672 (70, 2584)	1009 (273, 2160)	< 0.0001
Vaginal Delivery	304 (75.1%)	36 (54.6%)	0.001
Cesarean Section	84 (20.1%)	28 (42.4%)	0.0001

ADVERSE EVENTS			
	Oxytocin n=405	Foley Balloon n=66	p
Maternal Composite	62 (15.3%)	16 (24.2%)	0.07
Neonatal Composite	40 (9.9%)	7 (10.6%)	0.86

Tree Analysis of Maternal Outcomes



Tree Analysis of Neonatal Outcomes



## CONCLUSION

- Successful vaginal delivery rate (55%) is similar to other studies
- Maternal and neonatal adverse events are not increased when Foley balloon is used for cervical ripening
- Foley balloon is an acceptable method for cervical ripening in women with a history of cesarean section