INDUCTION OF LABOR

Abstracts 20-30

20 Induction of labor versus expectant management at 39 weeks: a cost-effectiveness analysis

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OBJECTIVE: A recent study found that induction of labor at 39 weeks for low-risk women was not associated with an increased risk of adverse neonatal outcomes. We sought to examine the cost-effectiveness and outcomes associated with induction of labor at 39 weeks versus expectant management.

STUDY DESIGN: A cost-effectiveness model using TreeAge software was designed to compare outcomes in women who were induced at 39 weeks versus expectantly managed. We used a theoretical cohort of 1.6 million women, the approximate number of nulliparous term births in the US annually that are considered low risk. Outcomes included mode of delivery, preeclampsia, macrosomia, intrauterine fetal demise, permanent brachial plexus injury, cerebral palsy, and neonatal death, in addition to cost and quality-adjusted life years (QALY) for both the woman and neonate. Probabilities were derived from the literature, and a cost-effectiveness threshold was set at $100,000/QALY.

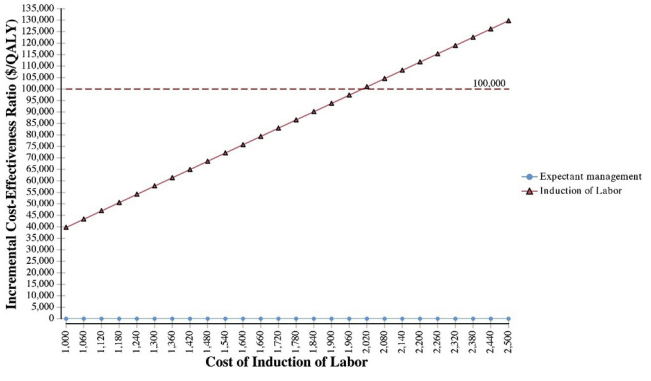
RESULTS: In our theoretical cohort of 1.6 million women, induction of labor resulted in 49,449 fewer cesarean deliveries and 79,152 fewer cases of preeclampsia. Additionally, we found that induction of labor resulted in 795 fewer cases of intrauterine fetal demise and 49 fewer neonatal deaths, despite 50 more cases of brachial plexus injury and 54 cases of moderate cerebral palsy (Table 1). Induction of labor resulted in increased costs, but increased QALYs with an incremental cost-effectiveness ratio of $97,501 per QALY. Univariate sensitivity analysis demonstrated that induction of labor was cost-effective until the cost of induction exceeded $2000 (Figure 1).

CONCLUSION: In our theoretical cohort, induction of labor in nulliparous term women at 39 weeks of gestation resulted in improved outcomes, but increased costs. The cost-effectiveness ratio was marginally cost effective, but would lead to an additional $2.26 billion of health care costs. Whether individual clinicians and healthcare systems offer routine induction of labor at 39 weeks will need to depend on local capacity and patient preferences.

Table 1. Outcomes in a theoretical cohort of 1.6 million pregnant women at 39 weeks of gestation.

	Induction of Labor	Expectant Management	Difference
Cesarean deliveries	313,706	363,155	-49,449
Preeclampsia	144,736	223,888	-79,152
Macrosomia	169,600	181,574	-11,974
Intrauterine fetal demise	0	795	-795
Permanent brachial plexus injury	3,085	3035	50
Moderate cerebral palsy	1,763	1,709	54
Neonatal death	189	238	-49
Cost (in thousands, USD)	$20,964,264	$18,700,990	$2,263,273
Effectiveness (in thousands, QALYs)	91,249	91,226	23
Incremental Cost-Effectiveness Ratio (ICER)	$97,501/QALY		

Figure 1. Univariate Sensitivity Analysis of the cost of induction of labor (WTP = $100,000/QALY)



21 A randomized controlled trial of pre-induction cervical ripening comparing dilapan-s versus foley balloon (DILAFOL trial)

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OBJECTIVE: To test the hypothesis that Dilapan-S is not inferior to the Foley balloon for pre-induction cervical ripening at term.

STUDY DESIGN: Pregnant women > 37 weeks with unfavorable cervix (<3cm and < 60% effaced) were randomly assigned to 12 hours of either Foley balloon (FB) inflated with 60 cc saline or Dilapan-S (DS) for cervical ripening. If cervix remained unfavorable, then one more round of the assigned dilator was used. Following ripening, oxytocin and labor management were left to the clinical providers. The primary outcome was vaginal delivery. Secondary outcomes are listed in Table. Patient completed a satisfaction survey after the pre-induction period. On the basis of noninferiority margin of 10% and a frequency of vaginal delivery of 76% in FB, a sample size of 420 women was needed (90% power & 87% protocol adherence).

RESULTS: From November 2016 – February 2018, 419 women were randomized (209 in FB; 210 in DS). In the intent to treat analysis,

vaginal delivery was more common in DS versus FB (81.3% vs 76.1%), with an absolute difference with respect to the FB of 6% (95%CI -2.1% to 13.9%) indicating noninferiority for the pre-specified margin. The difference was not large enough to show superiority (Figure). Noninferiority was confirmed in the per-protocol population (N=204 in FB, N=188 in DS), supporting the robustness of the results (Figure). Secondary outcomes were not different between groups, except for a longer time device remained in place in DS compared with FB (Table). Maternal and neonatal adverse events were not significantly different between groups. A priori interaction analyses showed no difference in the effect on vaginal delivery according to cervical dilation at randomization, parity, or BMI > 30 kg/m ^{2}. Patients in DS were more satisfied than patients in FB as far as sleep (P=0.01), relaxing time (P=0.001) and performance of desired daily activities (P=0.001).

CONCLUSION: Dilapan-S is non-inferior to Foley balloon for pre-induction cervical ripening at term. Advantages of Dilapan-S over Foley include FDA approval, safe profile, no protrusion from the introitus, no need to keep under tension and better patient satisfaction.

Figure. Absolute difference in vaginal delivery rate (with 95%CI) between Foley balloon and Dilapan-S in the intent to treat (ITT) and per-protocol (PP) analysis. The 95%CI spans zero but lies wholly above the Δ margin, indicating non-inferiority.

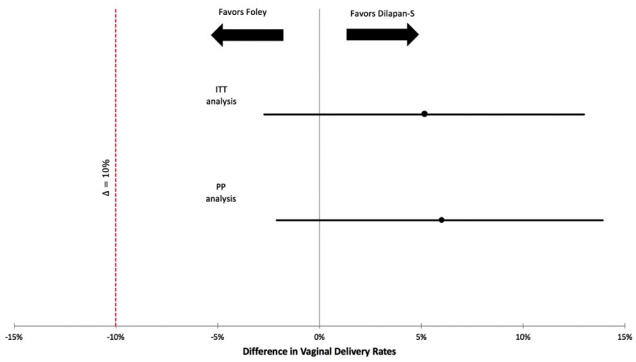

Table: Secondary outcomes by mechanical ripening group.

	Foley Group (n=209)	Dilapan-S Group (n=208)	*P value
Change in Bishop score	3 [-3 – 9]	2 [-2 – 11]	0.73
Operative vaginal delivery	6 (2.8)	10 (4.8)	0.3
Cesarean delivery	50 (23.9)	39 (18.8)	0.19
Time to active stage of labor^ (mins)	1011 [913-1074]	1152 [1092-1205]	0.21
Induction to delivery (mins)	565 [495-634]	678 [557-734]	0.64
Device placement to delivery (mins)	1291 [1203-1408]	1441 [1343-1521]	0.14
Hospital stay (hrs)	63 [59-67]	66 [64-69]	0.67
Total time device in place (mins)	666 ± 319	781 ± 281	0.0005
Regional anesthesia	188 (90.0)	174 (83.7)	0.05
Analgesia during cervical ripening	38 (18.2)	34 (16.7)	0.70

Data presented as n (%), median [Interquartile Range] or mean ± SD.
^Defined as cervical dilation >5cm.
** Chi-square or Mann-Whitney rank sum as appropriate.*

22 Transcervical ballon+vaginal misoprostol versus misoprostol for cervical ripening in nulliparous-obese women: a multicenter randomized trial

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OBJECTIVE: Nulliparous obese women are at increased risk for labor induction (IOL), unplanned cesarean delivery (CD) and adverse obstetric outcomes. Obesity has been associated with lower local prostaglandin sensitivity for cervical ripening. Our objective was to determine whether the combination of a transcervical Foley balloon and misoprostol (PGE1) is superior to PGE1 alone in decreasing the rate of CD in this population.

STUDY DESIGN: Pragmatic, multicenter, randomized, comparative-effectiveness trial (RCT, NCT02813551) of nulliparous obese (BMI ≥30 kg/m^2) women undergoing IOL from January 2016 to June 2018 at three academic hospitals. Inclusion criteria were: cephalic singleton gestation, intact membranes, gestational age ≥32 wks, and Bishop score (BS) <7. Major fetal anomalies, stillbirth or contraindications to PGE1 were excluded. Women were allocated to either 25 mcg of PGE1 plus a 26-Fr 60cc Foley balloon vaginally or 25 mcg of vaginal PGE1 alone every 4 h or until a BS >6 was achieved. Further labor management was at discretion of treating physicians. Primary outcome was rate of CD. Relevant secondary outcomes included: time from IOL to delivery, rate of composite maternal and neonatal outcomes. Sample size was determined based on a preliminary CD rate of 53%, with 80% power and alpha error of 0.05. Analyses were based on intention-to-treat.

RESULTS: Of the 236 women randomized, 113 (48%) received combined Foley balloon plus vaginal PGE1 and 123 (52%) received PGE1 alone. Baseline characteristics were analogous. Most common indications for IOL are depicted in Table 1. There was no difference in rate of CD between groups (45% vs 43%, p=0.75), and no differences in indications for CD (Table1). No differences were noted in the duration from IOL to delivery (24.82 ± 13.76 h vs 24.5 ± 14.0 h, p=0.87). In addition, the rate of composite maternal and neonatal adverse outcomes was similar (Table 2). There were no maternal or neonatal deaths.

CONCLUSION: In this RCT of nulliparous obese women, the rate of CD was similar irrespective of using vaginal PGE1 alone or in combination with a Foley balloon for IOL. Additional studies comparing different induction strategies are warranted.