

A RANDOMIZED CONTROLLED TRIAL

Barbara L. Wilson, PhD, RNC, Tammy Passante, BSN, RNC-OB, Diane Rauschenbach, BSN, RNC-OB, Rumei Yang, MS, and Bob Wong, PhD

#### **Abstract:**

Purpose: Many labor nurses routinely include continuous urinary catheterization (CC) as part of their standard care for women who receive intrapartum epidural anesthesia, to prevent urinary retention, thought to delay fetal descent. Recent studies question use of CCs during labor, as they may predispose patients to urinary tract infections (UTIs), even though the catheters are in place for a relatively short period of time. The objective of this study was to determine the influence of CCs versus intermittent catheters (ICs) (only as needed) on the duration of second stage of labor and the incidence of postpartum UTIs.

Study Design and Methods: Randomized controlled trial. English-speaking low-risk nulliparous women ≥37 weeks gestation with a single fetus in a vertex presentation who requested an epidural were eligible for participation. Prior to epidural placement, cervical status was documented, women were encouraged to void, and then women were randomized to receive either CC or IC as the method for urinary bladder management for the duration of the first stage of labor. Final sample size included 123 participants; 55 in the CC group and 68 in the IC group.

**Results:** No differences were noted in length of second stage labor, and the overall incidence of UTIs in both groups was low. There was a significantly increased likelihood of cesarean birth in women who had CC (P < .01) when compared to women who had IC. The overall cesarean rate in the CC group was 27.3%, versus 10.3% in the IC group.

**Clinical Implications:** Intermittent catheterization only as needed appears to be best practice for bladder management for laboring women with an epidural. There was a significantly higher rate of cesarean birth among women in the CC group. The relationship between route of birth and use of continuous indwelling urinary catheters for women in labor with epidurals for pain relief needs more study.

**Key words:** Birth; Cesarean birth; Intermittent urethral catheterization; Obstetric; Urinary bladder; Urinary catheterization.

pidural anesthesia and other pain-relieving drugs during labor are now common, particularly in many Western countries (Ullman, Smith, Burns, Mori, & Dowswell, 2010) including the United States. According to birth certificate data, more than 60% of women in the United States who had a singleton vaginal birth in 2008 received epidural or spinal anesthesia, and the rate for non-Hispanic White women who received epidural or spinal anesthesia was nearly 70% (Osterman & Martin, 2011). When compared with nonepidural or no analgesia in labor, epidural analgesia has been found to offer enhanced pain relief (Anim-Somuah, Smyth, & Jones, 2011). However, epidural analgesia and other regional analgesia are also known to carry significant adverse side effects during childbirth, including an increased risk of instrument-assisted birth (Indraccolo et al., 2011; Schrock & Harraway-Smith, 2012), decreased maternal gastric motility (Anderson, 2011), maternal hypotension (Hofmeyr, Cyna, & Middleton, 2004), prolonged second stage of labor (Cheng, Shaffer, Nicholson, & Caughey, 2014; Laughon et al., 2014; Sienko, Czajkowski, Swiatek-Zdzienicka, & Krawczynska-Wichrzycka, 2005; Weigl et al., 2010), and urinary retention (Simmons, Taghizadeh, Dennis, Hughes, & Cyna, 2012; Weiniger et al., 2006), among other adverse side effects.

The effect of urinary retention and a distended bladder on the length of labor and fetal descent is not completely clear. Earlier studies (Kerr-Wilson, Parham, & Orr, 1983; Read, Miller, Yeh, & Platt, 1980) found that a full bladder did not affect the course of established labor in women, noting that it was therefore unnecessary to catheterize patients in order to accelerate labor progress. However, intrapartum urinary retention does affect a significant number of childbearing women with epidurals compared to those without (up to 80%) (Weiniger et al., 2006), which may be one factor in why many labor and birth nurses continue the routine use of indwelling urinary catheters with epidurals.

The most appropriate type of catheter used for bladder management during labor (intermittent versus continuous) is not known. In an RCT, Evron et al. (2008) assigned intrapartum women to receive either a continuous catheter (CC/Foley) or intermittent catheter (IC/ straight catheter) via a controlled prospective singleblind trial (n = 209) and measured duration of second stage of labor, and the incidence of urinary tract infections (UTIs), and urinary retention. Women in the CC group needed higher doses of epidural medication in both the first and second stages of labor and experienced a significantly longer second stage of labor. Whether the higher doses of anesthetic in the CC group contributed to the longer duration of labor is not known, but is possible. In a more recent RCT, Rivard et al. (2012) compared indwelling versus intermittent catheterizations with 139 women with a singleton presentation in active labor or undergoing labor induction to determine whether a difference existed in time to birth from the interval between labor and birth admission and the birth of the newborn. They found the time to birth was similar in both groups, as was the route of birth and

birth cost estimates.

Hospital practices in the United States vary widely regarding bladder management strategies for women with epidurals, with many labor nurses routinely inserting an indwelling urinary catheter at the time of epidural placement as part of standard protocol, although no organizations or national practice guidelines recommend routine CC with epidurals, including the American Society of Anesthesiologists, the American College of Obstetricians and Gynecologists, and the Association of Women's Health, Obstetric and Neonatal Nurses (De Sevo & Semeraro, 2010). A UTI is the most common infection in hospitalized patients, accounting for as many as 40% of hospital-acquired infections (Institute for Healthcare Improvement, 2015; Meddings et al., 2014), and is one of the leading causes of postpartum fever, affecting 3% to 8% of all women following birth (National Institutes of Health, 2006). Therefore, determining appropriate bladder management for laboring women is of critical importance. Arguments for the ongoing use of CCs include: (a) concern about delayed fetal descent leading to higher cesarean rates;



Use of indwelling urinary catheters for women in labor with epidural analgesia is routine in some labor and birth units.



The potential link between use of an indwelling urinary catheter for women who have epidural anesthesia during labor and risk of cesarean birth needs further study.

(b) urinary retention and repeated ICs predisposing to postpartum UTIs; (c) increased nursing time to offer a bedpan repeatedly throughout labor or to catheterize the patient multiple times with ICs versus a one-time Foley catheter inserted with epidural placement and maintained throughout labor; and (d) nurses' preference for indwelling catheters.

Whether ICs or CCs during labor increase the incidence of postpartum UTIs is not well understood. In the RCT by Evron et al. (2008), laboring women with ICs versus CCs had the same incidence of UTIs and postpartum urinary retention, but another RCT (Millet, Shaha, & Bartholomew, 2012) found higher rates of bacteriuria in women with ICs versus CCs. In Millet et al.'s study, 146 singleton term low-risk women were randomized to either IC or CC with epidural placement. Two urine cultures were taken from each participant; the first following the initial catheterization at the time the epidural was placed; and the second on the day of discharge. The reported rates of postpartum bacteriuria were higher in the IC group, although most of

the patients with bacteriuria were asymptomatic. Additional empirical studies comparing both approaches are scant. Therefore, the purpose of this study was to determine the influence of IC versus CC on the duration of second stage of labor and the incidence of postpartum UTIs using an RCT design. We chose these two main outcome variables because they had been studied in the past in women having labor epidurals and either IC or CC with various results.

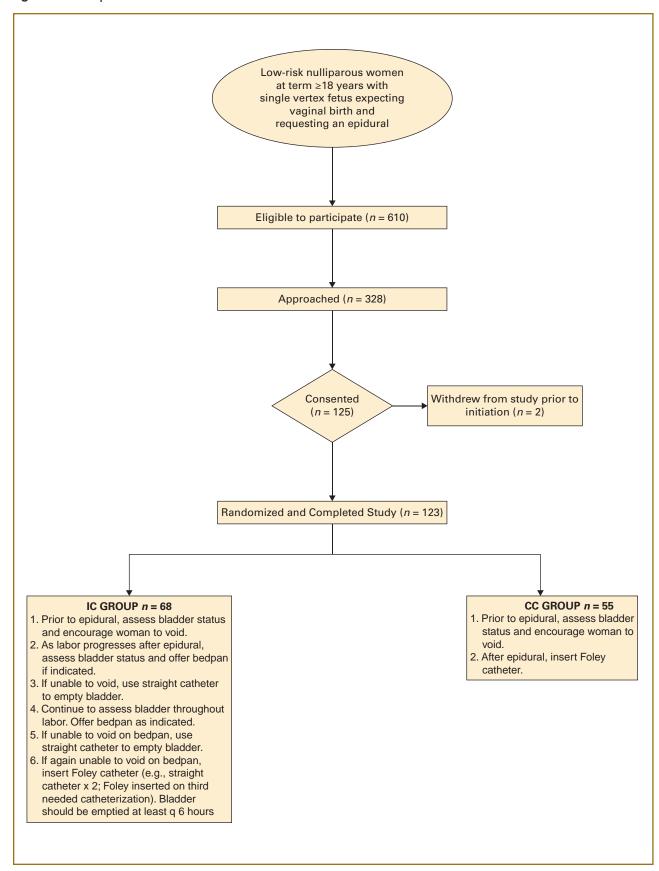
# **Methods**

After obtaining institutional review board approval, the study took place in the labor and birth unit in a community hospital with approximately 2,600 births per year in the Phoenix, Arizona metropolitan area. If an epidural was requested for labor pain relief, the patient's labor nurse determined whether study criteria were met and notified the labor and birth charge nurse who then spoke with the patient to explore their interest in the study. All labor and birth charge nurses completed the Collaborative Institutional Training Initiative program and received training on the study protocol and scripting for patient consent. Participation criteria included term (≥37 weeks) low-risk nulliparous women ≥18 years of age with a single fetus in vertex position who were requesting an epidural.

Prior to placement of the epidural, patients who had consented to participate were randomized into one of two groups via computer-generated codes maintained in sequentially numbered opaque envelopes to receive either intermittent catheterization as needed (IC Group) or a continuous indwelling catheter (CC Group). Women in

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Figure 1. Participant Flow



both groups were encouraged to void prior to epidural placement. Cervical status was documented and the primary nurse assigned to the patient proceeded as outlined in the algorithm (Figure 1). Nursing care for women in the IC group included bladder assessment as indicated; offering the bedpan as needed; if the woman was unable to void, then using a straight catheter to empty the bladder. Bladder assessment continued as labor progressed and the bedpan was offered as needed based on bladder status. Straight catheterization was allowed up to two times; if the bladder needed to be emptied again and the woman could not void on the bed pan, then a Foley catheter was inserted. Women in the CC group had a Foley catheter inserted immediately after the epidural. The Foley catheter was removed for all women prior to the initiation of second stage labor pushing. Following birth, the nurse caring for the patient returned the completed documentation forms to a designated secured box.

**Table 1.** Comparison of Demographics of Childbearing Women at Hospital Study Site and in Arizona in 2012.

Participating Hos	spital ( <i>n</i> = 2,607)		State ( <i>n</i> = 83,853)		
	Number	Percentage	Number	Percentage	
Race					
Hispanic	538	20.6%	32,807	39.1%	
Native American	47	1.8%	5,782	6.9%	
Non-Hispanic Asian	190	0.9%	3,303	3.9%	
Non-Hispanic Black	83	3.2%	3,976	4.7%	
Non-Hispanic White	1,740	66.7%	37,461	44.7%	
Other/unknown/missing	9	0.4%	97	0.1%	
Mother's Age					
Less than 15	1	0.0%	100	0.1%	
15–19	101	3.9%	8,316	9.9%	
20+	2,505	96.1%	75,430	90.0%	
Unknown/missing	0	0.0%	7	0.0%	
Method of Payment					
Medicaid	606	23.2%	44,501	53.1%	
Indian Health Services	11	0.4%	1,737	2.1%	
Private	1,908	73.2%	34,572	41.2%	
Self	82	3.1%	2,776	3.3%	
Unknown/missing	23	2.0%	267	0.3%	
Marital Status					
Married	1,987	76.2%	45,387	54.1%	
Not married	616	23.6%	37,597	44.8%	
Refused to answer	1	0.0%	549	0.7%	
Divorced	0	0.0%	49	0.1%	
Unknown/missing	3	0.1%	271	0.3%	

Study exclusion criteria included those women who were non-English speaking, not requesting an epidural, and who were high risk. Although risk categories are not absolute, for the purposes of this study high risk included women with obstetrical or medical complications including diabetes, gestational diabetes, hypertension, preeclampsia, fetal growth restriction, polyhydramnios, oligohydramnios, hematologic disorders, cardiovascular conditions (maternal heart disease), and maternal lung disease (King, Brucker, Fahey, Gegor, & Varney, 2015), which therefore excluded them from study participation.

Study participants in both groups received a follow-up phone call from one of the study principle investigators (PIs) at 7 to 10 days after discharge and were asked about signs or symptoms of a UTI since birth. The UTIs were determined only by participant self-report, where women were asked if they had experienced any of the following: a strong, persistent urge to urinate, a burning sensation when

urinating, painful or frequent urination, unusually strong-smelling urine, or cloudy urine. Participants were also asked if they had contacted their providers about a possible UTI. If women reported any signs or symptoms of a UTI but had not yet contacted their primary care provider, they were immediately referred back to their provider for appropriate follow-up.

# **Statistical Analysis**

Independent samples *t*-test were conducted to compare groups on continuous measures (maternal age, birthweight, cervical dilation, and effacement at placement of the epidural, length of second stage labor), whereas Pearson Chi-square was used in comparing presence of UTI, use of induction or augmentation of labor (Yes vs. No) between groups.

#### Results

The study was conducted between July 2012 and July 2013. Table 1 compares hospital and state demographics based on 2012 data. Childbearing women at the participating hospital were more likely to be non-Hispanic White (66.7% vs. 44.7%), married (76.2% vs. 54.1%), and privately insured (73.2% vs. 41.2%) than other women in the state.

A total of 610 healthy firsttime mothers were eligible to participate in the study. Of those, 328 were approached and 125 consented. Ultimately, 123 completed the study (2 dropped out

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**Table 2.** Comparisons of Groups by Maternal Age, Birthweight, Gestational Age, Augmentation, Induction, and Cervical Status

	Overall (n = 123) Mean (SD)	*IC ( <i>n</i> = 68) Mean (SD)	*CC ( <i>n</i> = 55) Mean (SD)	<i>p</i> -Value
Maternal age (years)	26.03 (4.70)	26.16 (4.76)	25.87 (4.66)	.74
Birthweight (grams)	3,463.74 (448.50)	3,445.7 (453.73)	3,486.1 (445.08)	.62
Gestational age (weeks)	39.75 (1.13)	39.74 (1.06)	39.77 (1.22)	.89
Induction (yes)	40 (32.52)	22 (30.99)	18 (34.62)	.61
Augmentation (yes)	55 (44.72)	31 (43.66)	24 (46.15)	.20
Induction (yes)	40 (32.52)	22 (30.99)	18 (34.62)	.61
Cervical dilation (cm) at placement of epidural	4.62 (1.33)	4.69 (1.33)	4.52 (1.35)	.49
Cervical effacement (%) at placement of epidural	90.08 (9.73)	91.41 (10.18)	88.23 (8.85)	.08

<sup>\*</sup>IC = intermittent catheterization: CC = continuous catheterization.

voluntarily prior to catheter placement); 55 in the CC group and 68 in the IC group, with no between-group differences noted in maternal age, cervical status at time of entry into study, labor induction or augmentation, newborn birthweight, or gestational age (Table 2). There was concern among the research team regarding the unequal distribution of group sizes (55 vs. 68) particularly given the nature of randomization and the study protocol. All data were reviewed and analyzed by the statistical team on multiple occasions, and co-PIs in the study met to ensure adherence to study protocol. No deviations from study protocols were noted.

Average age of study participants was 26.03 years (SD = 4.70); babies' birthweight 3,463.74 g (448.50); and average newborn gestational age was 39.75 weeks (SD = 1.13). There were no differences in basic demographic characteristics as shown in Table 2, indicating comparability between the IC and CC groups. Cervical status at the time of randomization was also comparable; in the IC group, mean cervical dilation was 4.7 cm (SD = 1.33) and mean cervical effacement was 91% (SD = 10.18) at the time they were initiated in the study protocol. In the CC group, mean cervical dilation was 4.5 (SD = 1.35) and mean cervical effacement was 89% (SD = 8.85) at the time they began study protocol.

Table 3 shows the outcomes of IC and CC on length of the second stage of labor and the number of UTIs in each group. There was no difference in length of second stage labor between groups (p = .807). Fourteen of the 55 women in the IC eventually had a Foley catheter inserted per protocol because they were unable to void on the bedpan and had been catheterized twice previously during labor with a straight catheter to empty their bladder.

As expected, the overall incidence of UTIs, whether actually diagnosed (n = 1) or based on self-reported symptoms from the follow-up phone call after discharge (n = 3) was low with 3 in the IC group and 1 in the CC

group. These did not vary significantly (p = .578), with post-hoc power analysis for this effect and sample size indicated power = 0.11. With low power we measured the number of UTIs and/or reported symptoms of UTIs as a point of discussion for clinical significance only. None of the four participants who reported a UTI and/or urinary discomfort at the follow-up phone call required catheterization once transferred to the postpartum unit

A surprising and incidental finding of statistical significance was the rate of cesarean birth between groups. Although the overall rate of cesarean section at the hospital is 25%, the rate for study participants was 10.3% in the IC group (n = 7) and 27.3% in the CC group (n = 15; p = .007). Reasons for cesarean birth in each group were documented as follows: in the IC group, failure to progress (n = 3), arrest of dilation (n = 2), and arrest of descent (n = 2). In the CC group, failure to progress (n = 3), arrest of dilation (n = 3), arrest of descent (n = 7), and abnormal (category III) fetal heart rate tracing (n = 2).

## Discussion

Regional analgesia, including spinal and epidural analgesia, has become a widely used method for the management of the pain during labor in the United States in the past 30 years. Compared with spinal analgesia, epidural analgesia is less likely to affect women's motor and sensory functions during the second stage of labor and has been considered more appropriate for labor analgesia. However, epidural analgesia increases risk of urinary retention more than nonepidural or no analgesia in labor; and urinary retention is believed to prevent the fetal head from descending and potentially prolonging labor. We did not see evidence of that concern in the current study: there was no difference in second stage length of labor between the IC and CC group. Urinary catheterization did not increase the incidence of

**Table 3.** Comparisons of Groups by Duration of the Second Labor Stage, Incidence of Postpartum UTIs or Self-Reported Symptoms of Bladder Discomfort Following Discharge, and Cesarean Section Rates

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	IC* <i>n</i> = 68	CC* n = 55	<i>p</i> -value	
Length of the second stage (minutes)	60.16 (53.94)	57.59 (44.077)	.807	
Urinary tract infections	3 (4.8%)	1(2.6%)	.578	
Cesarean birth	7 (10.3%)	15 (27.3%)	.007	

<sup>\*</sup>CC = continuous catheterization; IC = intermittent catheterization

postpartum UTIs or self-reported signs and symptoms of urinary tract discomfort, as reflected by the low rate of UTIs in both groups.

The Centers for Disease Control and Prevention (CDC) recommends intermittent catheterization at regular intervals rather than indwelling catheters for all patients, noting that urinary catheter use should be minimized altogether, particularly for patients at higher risk for catheter-associated urinary tract infections such as women (CDC, 2014; Gould, Umscheid, Agarwal, Kuntz, & Pegues, 2010). Laboring women do not meet the CDC criteria for insertion of an indwelling catheter, which includes: (a) acute urinary retention (sudden and painful inability to urinate) or bladder outlet obstruction; (b) to improve comfort during end-of-life care; (c) critically ill patients who need accurate measurements of intake and output; (d) surgical intraoperative monitoring or where large volumes of fluid or diuretics are anticipated; (e) selected surgical procedures, such as colorectal surgery or genito-urinary surgery; (f) to assist healing open sacral or perineal wounds in an incontinent patient; and (g) patients who experience prolonged immobilization (CDC, 2009). Our results imply that IC might be more reasonable than CC during labor for those women unable to void on their own. The concern of adverse effects from a potentially distended bladder (e.g., no indwelling catheter throughout labor) was not supported in this study: women in the IC and CC groups had comparable lengths of second stage of labor.

Most significant, we found that first-time mothers with a singleton in vertex position who had CC during labor had an increased likelihood of cesarean birth when compared to those with IC. Lengths of the second stage were comparable in both groups, excluding the effect of labor length on the incidence of cesareans. The higher likelihood of cesareans in the CC group was a surprising finding: women in both groups did not vary on maternal age, fetal birthweight, or gestational age (Table 2), and we made every attempt to minimize other mediating variables in our selection inclusion criteria (e.g., vertex presentation, singleton, maternal age, gestation). Although we could find no other studies demonstrating this same result, it has been observed that labor progression differs significantly for women who are induced versus those in spontaneous labor; and elective induction with an unfavorable cervix carries a higher risk of cesarean birth (Clark et al., 2009) even in term gestation (Vahratian, Zhang, Troendle, Sciscione, & Hoffman, 2005). We assessed women in each group to determine which were induced and/or had labor augmentation and found no differences between groups,

nor were we able to note differences in cervical status of the two groups (Table 2). The anesthesiologists used a standard dose of ropivacaine and fentanyl in the epidurals. It could be that there are other unknown variables that we failed to examine, which may in part account for the difference in cesarean rates between groups.

Another common concern during labor is the complication of postpartum UTI secondary to multiple catheterizations during labor. Our study did not reflect the differences between the groups because of the low incidences of UTI and/or reported signs and symptoms of urinary discomfort in both groups. As the diagnosis of UTI in our study was based on the patient's self-reported signs and symptoms 7 to 10 days after discharge, one may argue that the incidence of UTI in our study was greatly underestimated. However, because we were trying to examine the possibility of UTIs as a result of catheterizations, our study at least indicated that most of the UTIs during labor may not need medication (e.g., antibiotics), as the incidence of UTI based on women's self-reported symptoms was low (1.8%–4%).

### Limitations

Our study has several limitations. We were unable to use a blinded randomized controlled approach due to the nature of the study (using two distinct types of catheters and timing). Secondly, the diagnosis of UTIs was determined by women's report of subjective symptoms, which may actually underestimate the incidence of UTIs. A third limitation is the number of women who met study inclusion criteria that were not consented and therefore not included in the study. One possible reason includes resistance from the labor nurses to approach eligible patients due to the increased nursing time in performing frequent and comprehensive bladder assessments throughout labor as opposed to "usual care," which was indwelling catheter insertion with epidural placement. Another possibility for the low enrollment may be that the study PI was not on site and therefore unable to encourage participation or directly monitor recruitment of eligible patients. Regardless, the recruitment of eligible subjects was low and did not meet our expectations of sample size needed to obtain an effect size of .5, alpha of .05, and power of .95 to determine the effect of catheterization on length of second stage of labor (which would have required 100 participants in each group). In addition, we anticipated having adequate enrollment within 4 to 6 months; however, it was difficult to get nurses to participate in patient recruitment and we discontinued the study after 1 year.

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# **Suggested Clinical Implications**

Urinary tract infections are the most common infections in hospitalized patients, accounting for as many as 40% of hospital-acquired infections.

There is no difference in the length of the second stage of labor for nulliparous women with an epidural when comparing continuous indwelling catheters versus intermittent ("straight" catheters) during labor.

The CDC recommends intermittent catheterization at regular intervals rather than indwelling catheters for all patients, nothing that urinary catheter use should be minimized altogether.

We made no attempt to reach statistical significance in incidence of UTIs. With the low overall occurrence, we measured the number of UTIs and/or reported symptoms of UTIs as a point of discussion for clinical significance only.

The marked increase in the incidence of cesarean births in the CC group was an unexpected finding. It could be that other factors influenced likelihood of a cesarean birth that we did not account for, including length of time from admission to epidural placement, length of time the Foley catheter was in place, and length of first stage labor, among others. We did, however, confirm cervical status at the time of randomization and found the groups comparable, and every attempt was made to control for other potential confounders in the inclusion/exclusion criteria including fetal position, gestational age, maternal age, and maternal risk factors. Additionally, we were unable to compare the numbers of UTIs in study participants against overall UTI rates for obstetrical patients not involved in the study because the overall UTI rates after discharge are not tracked at this hospital. We recognized that the small overall occurrence of UTIs would make obtaining a sample size with statistical significance unrealistic.

A final limitation may be our ability to generalize findings to a broader population. Our study participants varied greatly from other childbearing women in the state (our participants were more likely to be married, insured, and non-Hispanic White). Additional research with a more diverse population is needed.

# Nursing Implications

Our study suggests that CCs may increase the likelihood of cesareans, but groups were comparable in both the length of second stage of labor and incidence of postpartum UTIs. Based on these findings IC is preferred to CC catheterization during labor for women with epidurals. However, urinary catheterizations in general should not be used routinely unless women are unable to void on their own. Women should not be catheterized for the convenience of hospital personnel; and this study suggests ICs may be the optimal strategy for women when catheterizations are needed during intrapartum for women with epidurals. Nurses should continue to assess bladder status throughout labor, offer the bedpan frequently, and only use IC for patients unable to void. •

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Barbara L. Wilson is an Associate Professor and Associate Dean of Academics, College of Nursing, University of Utah, Salt Lake City, UT. She can be reached via e-mail at barbara.wilson@nurs.utah.edu

Tammy Passante is a Perinatal Safety Coordinator and Clinical Supervisor, Labor and Delivery, Mercy Gilbert Medical Center, Gilbert, AZ.

Diane Rauschenbach is a Maternal Child Health Couplet Care RN, Mercy Gilbert Medical Center, Gilbert, AZ.

Rumei Yang is a PhD Student, College of Nursing, University of Utah, Salt Lake City, UT.

Bob Wong is an Associate Professor and Director of Applied Statistics, College of Nursing, University of Utah, Salt Lake City, UT.

The authors declare no conflict of interest.

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