

Use of phenazopyridine for reducing discomfort during embryo transfer

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Objective: The embryo transfer is a critical part of in vitro fertilization. When performed under abdominal ultrasound guidance, the embryo transfer procedure requires a full bladder. Patients often state that the discomfort of the distended bladder causes more pain than the actual transfer procedure. Phenazopyridine HCl is a bladder analgesic. The objective of this study was to determine if a single dose of phenazopyridine prior to embryo transfer reduces patient discomfort during that procedure.

Design: Prospective randomized double-blinded clinical trial.

Setting: University-based Reproductive Medicine practice.

Patient(s): Eighty-five reproductive age infertile women undergoing in vitro fertilization.

Intervention(s): Phenazopyridine (200 mg) or placebo taken 1 hour prior to embryo transfer utilizing transabdominal sonography.

Main Outcome Measure(s): Pain as assessed by visual analogue pain scale and physician and nurse assessment of patient discomfort.

Result(s): Study groups were similar in their demographic background. Mean pain score as assessed by a visual analogue pain scale during the procedure was 2.95 ± 2.4 in the placebo group, and 3.03 ± 2.6 in the active medication group (NS). There were also no significant differences in the observations of pain assessments.

Conclusion(s): Phenazopyridine used in a single dose prior to embryo transfer does not alleviate patient discomfort (Fertil Steril® 2007;87:1010–4. ©2007 by American Society for Reproductive Medicine.)

Key Words: Ultrasound, embryo transfer, pain, phenazopyridine

In vitro fertilization (IVF) is an established technology for helping couples conceive. In 2003, 48,000 babies were born as a result of assisted reproduction technology treatments accounting for >1% of all US deliveries (1).

An atraumatic, precisely placed embryo transfer is a critical step in the IVF process. The use of transabdominal ultrasound assistance to improve embryo transfer for IVF

was first described by Strickler et al. (2) in 1985 and Leong (3) in 1986. Its use has been shown in two meta-analysis to help improve pregnancy rates when compared to the clinical touch method (4, 5). Independent of any impact on pregnancy rates, ultrasound's ability to permit visualization of the transfer catheter provides reassurance to both the clinician and patient (2, 6, 7). Ultrasound may also be useful to help map out the position of the uterus, which may change from the time of the mock transfer (8), decrease the frequency of difficult transfers (9), as well as improve pregnancy rates by facilitating the correct positioning of the catheter within the uterine fundus (10).

The use of the transabdominal ultrasound requires a full bladder to aid visualization. The distended bladder may also help ease the passage of the transfer catheter via its effect on straightening an anteverted uterus. However, discomfort associated with the ultrasound has been reported in the literature (11), and we find that approximately one third of our patients complain of significant discomfort from their full bladder, especially with the ultrasound transducer being pressed down on the abdomen. Over half of these women state that the pain associated with the full bladder is worse than any discomfort associated with the embryo transfer

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Commercial product mentioned in title: Phenazopyridine HCl (Pyridium; Parke Davis, Morris Plains, New Jersey).

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itself. Independent of the improved ability to view the uterus with a full bladder noted clinically, consideration could be given to not filling the bladder. However, a randomized trial comparing a full to an empty bladder in women utilizing transabdominal guidance during embryo transfer revealed a higher likelihood of needing to use a tenaculum, obturator, and/or sound if the bladder was not filled (11).

Phenazopyridine HCl (Pyridium; Parke Davis, Morris Plains, NJ) exerts a topical analgesic effect on the mucosa of the urinary tract, with its precise mechanism of action remaining unknown. It is a category B medication, and is employed frequently in pregnancy. In addition to its long history of use for urinary tract infections and interstitial cystitis, phenazopyridine is indicated to relieve pain, burning, urgency, or frequency caused by trauma, surgery, and examination procedures (12–14).

In both speaking to the manufacturer (Park Davis) of phenazopyridine as well as performing a literature, Web, and textbook search, we were not able to find any data addressing the use of phenazopyridine during embryo transfer or to help with the discomfort of a full bladder associated with the use of an abdominal probe ultrasound. The purpose of this study

was to investigate whether administration of phenazopyridine prior to ultrasound-guided embryo transfer reduces patient discomfort during that procedure.

MATERIALS AND METHODS

This prospective randomized double-blind clinical trial was approved by the Institutional Review Board at Women & Infants' Hospital. Exclusion criteria included an unwillingness to participate in the study, a history of an allergy to phenazopyridine, a history of G6PD deficiency, or a history of liver or kidney disease. A power analysis was performed based on 80% power and a type I error of .05. For the power calculation, pain as assessed by the visual analogue pain scales (VAS) of 10 patients undergoing embryo transfer was used. The average pain score, on a scale of 0 to 10, was 3. To reduce this level of pain by 20%, a clinically significant amount, 175 patients were required in each arm. The primary study outcome was pain as measured by the VAS. Secondary outcomes included pain as assessed by physician and nurse observers, ease of embryo transfer, bladder volume (measured by amount of urine voided), and clinical pregnancy rates.

TABLE 1

Patient characteristics by treatment group.

	Placebo N = 42	Phenazopyridine N = 41	P value
Age (mean ± SD) (N = 41, 38)	34.8 (4.9)	34.5 (5.5)	.81
Race/ethnicity (N = 42, 41)			
White	34 (81)	34 (83)	.45 ^a
Black	1 (2)	0	
Hispanic	0	1 (2)	
Asian/Pacific Islander	4 (10)	1 (2)	
Not known/other	3 (7)	5 (12)	
BMI (mean ± SD) (N = 36, 37)	26.5 (6.5)	26.7 (6.1)	.90
Ever pregnant (N = 41, 38)	19 (46)	22 (58)	.30
Any children (N = 41, 37)	9 (20)	12 (32)	.19
Painful periods (N=41, 38)	26 (63)	21 (55)	.46
Chronic pelvic pain (N = 41, 38)	3 (7)	4 (11)	.71 ^a
Interstitial cystitis (N = 41, 38)	0	1 (2)	.48 ^a
Frequent UTI (N = 41, 38)	1 (2)	0	1.00
Usual time between voids (N = 41, 38)			
<1 hour	1 (2)	4 (11)	.17 ^a
1–2 hours	9 (22)	12 (32)	
2–3 hours	12 (29)	13 (34)	
3–4 hours	11 (27)	7 (18)	
>4 hours	8 (20)	2 (5)	
Voided after taking study medication (N = 37, 34)	3 (8)	3 (9)	1.00 ^a
Has taken phenazopyridine in the past (N = 41, 38)	11 (27)	2 (5)	.01 ^a
Believes took phenazopyridine (n = 21, 21)	12 (57)	13 (62)	.75

^a P value from Fisher's exact test.

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