January 2003

Increased risk of cervical canal infections with intracervical foley catheter

S Siddiqui
Aga Khan University

NF Zuberi
Aga Khan University

Afia Zafar
Aga Khan University, afia.zafar@aku.edu

RN Qureshi
Aga Khan University

ORIGINAL ARTICLE

INCREASED RISK OF CERVICAL CANAL INFECTIONS WITH INTRACERVICAL FOLEY CATHETER

Salva Siddiqui, Nadeem Faiyaz Zuberi, Afia Zafar* and Rahat Najam Qureshi

ABSTRACT

Objective: To evaluate the effect of intracervical Foley catheter insertion, for the induction of labor, on cervical canal infection.

Design: A prospective interventional study with paired analysis.

Place and Duration of Study: The study was conducted in the department of Obstetrics and Gynecology at the Aga Khan University, Karachi, between June 1 and August 31, 2002.

Subjects and Methods: In 45 women undergoing cervical ripening with intracervical Foley catheter for the induction of labour at term, cervical swabs were taken for culture and sensitivity before its insertion and again after its spontaneous expulsion or removal.

Results: Intracervical Foley catheter was retained for mean duration of 8.1 ± 1.7 hours. There was a significant change in the pathogenic organisms (0 % v 16.3 %; p 0.016) from pre-Foley to post-Foley catheter cervical swab cultures. Growth of *β-hemolytic Streptococcus* group-B, *Candida albicans, Candida glabrata and Gardnerella vaginalis* on cervical swab were considered pathogenic. One woman (2.2 %) developed fever following insertion of intracervical Foley catheter. No statistically significant effect of potential confounding factors was observed on change in growth of pathogenic organisms.

Conclusion: Induction of labour at term with Foley catheter is associated with a significant increase in intracervical pathogenic organisms despite undertaking routine aseptic measures. We recommend evaluation of this technique for its potential infectious harm in larger studies. Meanwhile, extreme aseptic measures should be undertaken during its insertion to avoid maternal and possible neonatal infections.

KEY WORDS: *Labor, Induced. Foley balloon catheterization. Infection maternal. Infection neonatal.*

INTRODUCTION

The use of a Foley catheter to effect cervical ripening was first described by Embrey and Mollison in 1967.[1] Cervical ripening with extra-amniotic balloon catheters possesses the advantages of simplicity, low cost, reversibility and lack of severe side effects.[2] Balloon catheters can theoretically lead to ascending infection due to mechanical interruption of cervical canal and extra-amniotic space along with bleeding due to local trauma. Significant infectious complications, arising from this technique in either the mother or the newborn have not been witnessed [3, 4-7] Most series reported very few side effects of cervical ripening by a Foley catheter balloon; the most common being intrapartum or postpartum fever and vaginal bleeding after insertion.[1, 6-9] Febrile morbidity may be present in less than 10 percent of the patients.[10]

There is absence of substantial evidence in the literature regarding the changes that can occur in cervical and vaginal flora after intracervical insertion of Foley catheter. A recent Cochrane review, which evaluated the effectiveness of mechanical methods to ripen the cervix has not included this issue as an outcome measure due to unavailability of information.[11] At our institute cervical ripening with extra-amniotic Foley catheter is one of the most frequent methods used for induction of labour. Some vaginal bleeding after intracervical insertion of Foley catheter is a common observation.

This study aimed to evaluate the effect of intracervical Foley catheter insertion, for induction of labour, on risk of increasing pathogenic organisms in cervical canal.

PATIENTS AND METHODS

Forty-five women were included in the study who were undergoing cervical ripening with extra-amniotic Foley catheter balloon for the induction of labour at term in the department of obstetrics and gynecology, The Aga Khan University, Karachi. The study included all eligible women between 1st June and 31st August 2002, who gave an informed written consent. Women having fever, vaginal infection or discharge were excluded from the study.

The vaginal portion of uterine cervix was exposed with sterile speculum. After thorough cleaning of vagina and cervix with povidone iodine solution, a 16-22 gauge Foley catheter was inserted into the endocervix under direct vision and passed above the level of the internal os. The balloon was inflated with 30 ml to 50 ml of sterile saline and pulled gently to the level of internal os, where it was left for 4 to 12 hours or until spontaneous expulsion. Cervical swabs were taken for culture and sensitivity before the insertion. Repeat cervical swabs were taken after spontaneous expulsion or removal of intracervical Foley catheter.

Department of Obstetrics and Gynecology, The Aga Khan University, Karachi.

* Department of Microbiology/Pathology, The Aga Khan University, Karachi.

Correspondence: Dr. Nadeem Faiyaz Zuberi, Department of Obstetrics and Gynaecology, The Aga Khan University, Stadium Road, Karachi-74800, Pakistan.E-mail:nadeem.zuberi@aku.edu

Received September 28, 2002 ; accepted February 10, 2003.

These swabs were taken in the labour room and sent to microbiology laboratory within an hour for culture and sensitivity in commercially prepared transport swab (Transwab ® supplied by Medical Wire and Equipment Company, England). All submitted samples were directly inoculated and incubated under standard conditions for the isolation of bacteria, *Candida albicans* and its other species. Suspicious colonies were identified by conventional biochemical and serological tests. All these cultures were monitored and interpreted by one of the authors and reported. In case of positive culture, primary attending and pediatrician were informed and patients were offered antibiotic treatment.

We evaluated effect of maternal age, parity, gestational age, insertion-expulsion/removal interval of intracervical Foley catheter, on probability of increasing pathogenic organisms in post-Foley catheter culture swab as compared to the pre-Foley catheter culture swab and occurrence of fever within 24-hours of insertion of intracervical Foley catheter.

A sample size of 68 was required to achieve 80% power (1-β) to detect the 10% increase in the rate of pathogenic organisms in cervical flora as compared to before the insertion of intracervical Foley catheter with 5% level of significance (α). Forty-five patients were recruited in the study as funding was available for these many patients. Descriptive statistics are presented as means ± standard deviation, median with range, and numbers as percentages or proportions. Associations between predictor and outcome variables are presented as relative risks. Univariate analysis for correlated proportions was done with McNemar's paired test. Difference between pathogenic organism in pre and post Foley catheter cervical swab cultures was calculated with this test. The study was carried out after approval by Ethical Review Committee (ERC) of Aga Khan University and was funded by Postgraduate Medical Education (PGME) Research Grant.

RESULTS

The patients were compared with respect to their pre and post Foley catheter cervical swab cultures and their study characteristics are given in Table I. There was statistically significant difference in growth of pathogenic organisms in pre and post Foley catheter cervical swab cultures on paired analysis (Table II). Only the culture results that have change in their pathogenic organisms (0 % v 16.3 %; p 0.016) were used in computing Mc Nemar's test.

Pathogenic organisms were identified as ones which can potentially cause maternal and/or neonatal infection (Table III). Prevalence of *β-hemolytic Streptococcus* group-B was 6.7% (n=3/45) in pre-Foley group and of *Candida albicans/glabrata* was 8.9 % (n=4/45). Despite cleaning the cervix with povidone iodine solution and taking an intracervical culture under direct vision avoiding contact with vaginal mucosa, 62.2% (n=28 / 45) of pre-Foley culture swabs grew normal vaginal flora.

There were no statistically significant effect of potential confounding factors like advanced maternal age, obesity, anemia, abnormal gestational diabetes screen, unfavorable cervical findings, vaginal birth after cesarean (VBAC), and retention of intracervical foley for longer duration on growth of pathogenic organisms (Table IV).

One woman had fever after insertion of Foley catheter for which no other reason could be identified. Primary obstetricians and pediatricians were informed about the culture results if they were positive for pathogenic organisms and patients were given appropriate treatment.

Table I: Characteristics of study population. n=45

Factors	Mean ± SD	Range
Age (years)	28.4 ± 5.1	18-40
Height (meter)	1.58 ± 0.1	1.31-1.88
Weight (kg)	69.2 ± 10.6	51.0-97.4
BMI	27.8 ± 4.2	17.1-38.5
Hb (gm/dL)	11.2 ± 1.2	7.0-13.2
GCT (mg/dL)	109.8 ± 17.4	87-173
Parity	1.5 ± 0.6	1-3
Bishop score	3.5 ± 1.7	0-7
Foley's duration (hours)	8.1 ± 1.7	2.3-12

Table II: Intracervical growth of pathogenic organisms with extra-amniotic Foley catheter balloon. n=43*

	Post-Foley		
	Pathogenic organisms	Non-pathogenic organisms/no growth culture	p-value
Pre-Foley			
Pathogenic organisms	7 (16.3 %)	0 (0 %)	0.016 **
Non-pathogenic/on growth	7 (16.3 %)	29 (67.4 %)	

*Culture results for 2 samples were not available (1 each from pre-Foley and post-Foley groups). **Mc Nemar Test

Table III: Spectrum of intracervical growth of organisms on pre and post Foley cervical culture swabs. n= 45

	Pre-Foley culture (n=45)	Post-Foley culture (n=45)	RR(95% CI)	p-value
Pathogenic organisms	**7 (15.6 %)**	**14 (31.1 %)**	**1.63 (0.95-2.78)**	**0.05**
Beta hemolytics group B	3	5		
Gardnerella vaginalis	0	1		
Candida albicans/gabralda	4	8		
Non-pathogenic organisms	**31 (68.9 %)**	**28 (62.2 %)**	**1.11 (0.94-1.32)**	**0.20**
Mixed bacterial flora	3	5		
Normal vaginal flora	28	23		
No growth	**6 (13.3 %)**	**2 (4.4 %)**	**Reference category**	
Missing results	**1 (2.2 %)**	**1 (2.2 %)**		

Table IV: Potential confounding factors influencing presence of pathogenic organisms before insertion of intracervical Foley catheter balloon. n=44*

Risk factors	Pathogens present	Nonpathogens present	RR (95% CI)	p-value
Advanced maternal age (≥35 years)	0	6	0	
Age <35 years (reference)	6	32	0-6.76	0.57
Obesity (BMI ≥24)	4	33	0.38	
BMI <24 (reference)	2	5	0.09-1.68	0.24
Anemia (Hb <11gm/dL)	2	12	1.07	
Hb ≥11gm/dL (reference)	4	26	0.22-5.17	1.00
Abnormal **GDM screen (GCT ≥140mg/dL)	1	2	2.47	
GCT <140mg/dL (reference)	5	32	0.41-14.86	0.39
Primigravidity	3	18	1.00	
Multiparity (reference)	3	20	0.25-4.85	1.00
Unfavorable cervix (Bishop <6)	5	37	0.24	
Bishop ≥6 (reference)	1	1	0.05-1.19	0.26
Pre-eclampsia (PET)	1	5	1.27	
Normotensive (reference)	5	33	0.18-9.05	1.00
Vaginal birth after cesarean (VBAC)	1	6	1.27	
No previous cesarean delivery (reference)	5	32	0.14-7.73	1.00
Prolong retention of foleys (≥6 hours)	6	35	-	
Retention of foleys <6 hours (reference)	0	3		1.00
Foleys deflated for removal	6	33	-	
Spontaneous foleys expulsion (reference)	0	5		1.00

*Culture result for 1 sample of pre-Foley group was not available.
**GDM = Gestational diabetes mellitus.
+GCT = glucose challange test.

Discussion

This study showed an increase in 16 % of pathogenic organisms in cervix after insertion of Foley catheter for induction of labour even after adjusting for potential risk factors. The risk was significantly higher for infection with *β-hemolytic Streptococcus* group-B and *Candida albicans/glabrata.* Studies comparing Foley catheter with other methods for the induction of labour have focussed on its economics and effectiveness for cervical ripening, but have not addressed its potential of increasing chances for infection. [2, 13-17]

Our study is the first to show this association in a comparative study. The most commonly encountered infections specific to pregnancy and the puerperium are usually the result of ascending contamination of the uterine cavity and its contents by the lower genital tract flora. Many female pelvic infections involve a mixture of aerobic and anaerobic organisms. Among the aerobic organisms, *β-hemolytic Streptococcus* group-B and *Gardnerella vaginalis* were encountered in our study. Anaerobes are notoriously difficult to isolate, and most hospital laboratories are unable to replicate the specialized techniques of research laboratories dedicated to this activity.[18] Swabs are not recommended to process anaerobic organisms as these organisms are fastidious and their yield is very poor from them. Therefore anaerobe isolation was not considered in this study.

Under normal conditions, the vaginal flora comprises a wide variety of organisms, including staphylococci, streptococci, enterococci, lactobacilli, diphtheroids, *Escherichia coli,* anaerobic streptococci, *Bacteroides* and *Fusobacterium* species, with peroxide-producing lactobacilli dominating.[19] Pathogenic organisms like *Escherichia coli, Staphylococcus hemolyticus, Chlamydia trachomatis* and *Ureaplasma urealyticum* are isolatable from the cervical swab in 28% of healthy pregnant women.[20]

In this study, intracervical Foley catheter was inserted under direct vision after cleaning the vagina and cervix using standard technique.[2] Despite this, we encountered pathogenic organisms in 15.6% of pre-Foley swabs, which is a matter of concern, indicating ineffectiveness of cleansing procedures in eliminating pathogenic organisms from cervix. Reduction in culture of normal vaginal flora in our study is attributable to the relative increase in pathogenic organisms in swabs in which previously either there was no growth or only of non-pathogenic organisms. Our study highlighted the importance of appropriately balancing economics and effectiveness of Foley catheter for the induction of labour with increased risk of infection.

Conclusions

Cervical ripening with intracervical Foley catheter possesses the risk of increasing the pathogenic organisms in the cervical canal. The majority of reported series about cervical flora have not addressed this issue. Although there is widespread use of intracervical Foley as an economical method for induction of labour in developing countries, the risk of infection needs to be weighed and the role of antibiotics is to be explored. Finally, we emphasize that this method should be adopted with extreme aseptic measures.

Acknowledgements: We are extremely grateful to the ladies, who participated in this study, the doctors, nursing and microbiology laboratory's technical staff who assisted in obtaining and processing the culture swabs; and Postgraduate Medical Education Department of Aga Khan University for providing the Research Grant funding, without which this study would not have been possible.

References

1. Embrey MP, Mollison BG. The infavourable cervix and induction of labour using a cervical balloon. *J Obstet Gynaecol* (Br Commonw) 1967; **74**: 44.
2. Riskin-Mashiah S, Wilkins I. Cervical ripening. *Obstet Gynecol Clin North Am* 1999; **26**: 243-57.
3. Atad J, Hallak M, Auslender R, Porat-Packer T, Zarfati D, Abramovici H. A randomised comparison of prostaglandin E2, oxytocin, and double-balloon device in inducing labor. *Obstet Gynecol* 1996; **87**: 223-27.
4. Hemlin J, Moller B. Extra-amniotic saline infusion is promising in preparing the cervix for induction of labor. *Acta Obstet Gynecol Scand* 1998; **77**: 45.
5. Lyndrup J, Nickelsen C, Weber T, Molnitz E, Guldback E. Induction of labor by balloon catheter with extra-amniotic saline infusion (BCEAS): a randomised comparison with PGE2 vaginal pessaries. *Eur J Obstet Gynecol Reprod Biol* 1994; **53**:189-97.
6. Rouben D, Arias F. A randomised trial of extra-amniotic saline infusion plus intracervical Foley catheter balloon versus prostaglandin E2 vaginal gel for ripening the cervix and inducing labor in patients with unfavourable cervices. *Obstet Gynecol* 1993; **82**: 290.
7. Schreyer P, Sherman DJ, Ariely S, Herman A, Caspi E. Ripening the highly unfavorable cervix with extra-amniotic saline instillation or vaginal prostaglandin E2 application. *Obstet Gynecol* 1989; **73**: 938-42.
8. Lieberman JR, Piura B, Chaim W, Cohen A. The cervical balloon method for induction of labor. *Acta Obstet Gynecol Scand* 1977; **56**: 499-503.
9. James C, Peedicayil A, SeshadriL. Use of the Foley catheter as a cervical ripening agent prior to induction of labor. *Int J Gynaecol Obstet* 1994; **47**: 229.
10. Sherman DJ, Frenkel E, Tovbin J, Arieli S, Caspi E, Bukovsky I. Ripening of the unfavorable cervix with extra-amniotic catheter balloon: clinical experience and review. *Obstet Gynecol Surv* 1996; **10**: 621-27.
11. Boulvain M, Kelly A, Lohse C, Stan C, Irion O. Mechanical methods for induction of labor (Cochrane review). In: The Cochrane Library, 2003 Issue **1**,. Oxford: (update software).
12. Barrilleaux PS, Bofill JA, Terrone DA, Magann EF, May WL, Morrison JC. Cervical ripening and induction of labor with misoprostol, dinoprostone gel, and a Foley catheter: a randomized trial of 3 techniques. *Am J Obstet Gynecol* 2002; **186**: 1124-9.
13. Levy R, Ferber A, Ben-Arie A, Paz B, Hazan Y, Blickstein I, *et al.* A randomised comparison of early versus late amniotomy following cervical ripening with a Foley catheter. *BJOG* 2002; **109**: 168-72.
14. Sciscione AC, Muench M, Pollock M, Jenkins TM, Tildon BJ, Colmorgen GH. Transcervical Foley catheter for preinduction cervical ripening in an outpatient versus inpatient setting. *Obstet Gynecol* 2001; **98**: 751-6.
15. Greybush M, Singleton C, Atlas RO, Balducci J, Rust OA. Preinduction cervical ripening techniques compared. *J Reprod Med* 2001; **46**: 11-7.

16. Mazhar SB, Sarwar S, Mahmud G. Induction of labour, a randomized trial comparing prostaglandin E_2 pessary, intracervical Foley catheter and extra amniotic saline infusion. *J Surg* (PIMS) 2000; **19**-20: 12-8.
17. Mazhar SB, Alam K. Induced labour: indications and outcome experience (PIMS). *J Surg* 2001; 23-24: 31-33:
18. American College of Obstetricians and Gynecologists. Antimicrobial therapy for obstetric patients. ACOG educational bulletin 245. Washington, DC: *ACOG* t998.
19. Guaschino S, De Santo D, De Seta F. New perspectives in antibiotic prophylaxis for obstetric and gynaecological surgery. *J Hosp* Infect 2002; **50** (suppl A): S 13-6.
20. Curzik D, Drazancic A, Hrgovic Z. Nonspecific aerobic vaginits and pregnancy. *Fetal Diagn Ther* 2001; **16**: 187-92.