Pre-induction cervical ripening by Foley's catheter in relative indication of cesarean section

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Abstract

Introduction: The rate of caesarean section (CS) has continued to rise upward. Many complications could occur during C-section. The balloon catheter, including Foley's single-balloon catheter, appears to be a widely accepted mechanical method and is recommended by the WHO for the normal vaginal induction process. Aim of the work: To evaluate the success rate of pre-induction cervical ripening with Foley's catheter in cases of relative indication for caesarean section and increase rate of vaginal delivery within 24 hours in Tobruk-Libya. Patients, Materials and Methods: Prospective case control study in Gynecology and Obstetrics department at Tobruk Medical Center, Libya from January 2020 to December 2020. The study group include 146 selected cases of relative indications for caesarean section: (10) cases of grand multi (controlled HTN - controlled DM - cardiac cases), (6) cases of multigravida breech, (20) cases of oligohydramnios (AFI-3-4cc) In grand multi, (24) cases of grand multi post-date and (86) cases of previous C/S (PROM, post-date and with medical cardiac disease as DM - HTN). Women scheduled for induction of labor between 37-41 weeks of gestation admitted to maternity with singleton. Results: Most of patient expel within 4-6 hours and bishop score obtained then amniotomy done. Most of them were delivered without augmentation. Few cases need augmentation by 1 unite syntocinon. A few cases failed and did not expel the catheter and shifted to C/S. Very few cases are complicated by chorioamnionitis. Total cases are 146 with 132 (90.4 %) cases delivered normal within 24 – 48 hours while 14 (9.6 %) cases ended by C/S Conclusion: Cervical ballooning by Foley's catheter is a pre-induction safe method, efficient, and offering potential to increase the rate of vaginal deliveries in pregnant women with relative indication for cesarean section

Keywords: Cervical ripening; Foley's catheter; cesarean section.

Introduction

Over the past decade, the rate of caesarean section (CS) has continued to rise upward [1]. According to the World Health Organization global survey, the CS rate varies widely according to the geographical regions, with country-level rates ranging from less than 10% to more than 50%. [2–4] Although evidence has shown CS can reduce risks of maternal and perinatal mortality and morbidity, [5,6] the long-term risks and benefits of CS, especially without medical indications, remain unclear [7,8]. The reasons for the rise in the rate of cesarean sections have fully understood [9]. However, some causative reasons are old age of women especially those without any children [10], women with fewer children, fetuses in the breech position, prevalence of obesity, women with preeclampsia and in the 40th week of pregnancy [11]. Many complications could be occurred during C-section as entrapment of the fetus's head within the pelvis, rupture of the cervix with bleeding, damage to the uterine vessels in the low uterus segment incision, bleeding from the placental bed, uterine atony, damage to the bladder, damage to the ureter and bowel, and thromboembolism [12]. Tachypnea, infantile respiratory distress syndrome, hospitalization of the neonate in the intensive care unit (ICU) [13] and the

complications associated with anesthesia [14]. Methods used for cervical ripening can be broadly divided into mechanical devices and pharmacologic options [15, 16]. The balloon catheter, including Foley's single-balloon catheter, appears to be a widely accepted mechanical method and is recommended by the WHO for the induction process [17]. Mechanical ripening devices apply pressure to the internal face of the cervix, directly overstretching the lower uterine segment and indirectly increasing the localized secretion of prostaglandin. In addition to the local effect, mechanisms that involve neuroendocrine reflexes (such as the Ferguson reflex) may promote the onset of contractions [18]. Due to increased incidence of cesarean sections in Tobruk, Libya, I was able to evaluate the success rate of pre-induction cervical ripening with Foley's catheter in cases of relative indication for caesarean section and increase rate of vaginal delivery within 24 hours.

Patients, Materials and Methods

The present study is a case control prospective study in Gynecology and Obstetrics department at Tobruk Medical Center, Libya from January 2020 to December 2020.
The study group include 146 selected cases of relative indications for caesarean section which include:

- Ten (10) cases of grand multi (controlled HTN - controlled DM - cardiac cases).
- Six (6) cases of multigravida breech.
- Twenty (20) cases of oligohydramnios (AFI-3-4cc) In grand multi.
- Twenty-four (24) cases of grand multi post-date.
- Eighty-six (86) cases of previous C/S (PROM, post-date and with medical disease as cardiac disease, DM and HTN)

Women scheduled for induction of labor between 37-41 weeks of gestation admitted to maternity with singleton. Alive or died with bishop score less than 4 – intra cervical single balloon (20-22 fr) inflated with 70-80 cc normal saline with good traction on medial aspect of thigh other patient were excluded as antepartum hemorrhage, non-reassuring CTG, previous myomectomy, T- shop incision, multi scars. Catheter kept 12-24 hours under cover of antibiotics.
Ethical considerations: permissions were obtained from the research ethical committee of Tobruk University to perform the study.

Statistical Analysis

In the process of statistical analysis, the collected data underwent coding, followed by entry and examination utilizing SPSS version 22 (Statistical Package for Social Science). Descriptive statistics were employed for categorical variables, presenting frequency and percentage, while numerical variables were represented in terms of mean and standard deviation (mean ± SD). To assess significance, appropriate statistical tests were applied, including the Chi-Square ($\chi 2$) test for categorical data. P-values equal to or less than 0.05 were considered indicative of statistical significance.

Results

Most of patient expel within 4-6 hours and bishop score obtained then amniotomy done. Most of them were delivered without augmentation. Few cases need augmentation by 1 unite syntocinon. A few cases failed and did not expel the catheter and shifted to C/S. Very few cases

are complicated by chorioamnionitis. Total cases are 146 with 132 (90.4 %) cases delivered normal within 24 – 48 hours while 14 (9.6 %) cases ended by C/S (Table-1).

Case	Number	Fate	Complications
Previous C/S PROM	43	2cases of VBAC ended by c/s	3 cases chorioamnionitis and delivered vaginally
Previous C/S post date	28	2 cases VBAC ended by C/S	
Previous C/S with medical disease as HTN - DM - antiphospholipid	15	5 cases ended by C/S	
Grand multi-PROM - oligohydramnios	20	1cases ended by C/S	2 case chorioamnionitis and delivered vaginally
Grand multi post date	24		
Breech - grand multi post date	6	3 cases ended by C/S	
Grand multi with medical disease (HTN - DM - cardiac)	4 - HTN 5 - DM 1 - Cardiac	3 cases ended by C/S	

Table (1): Number of cases with their fate and complications.

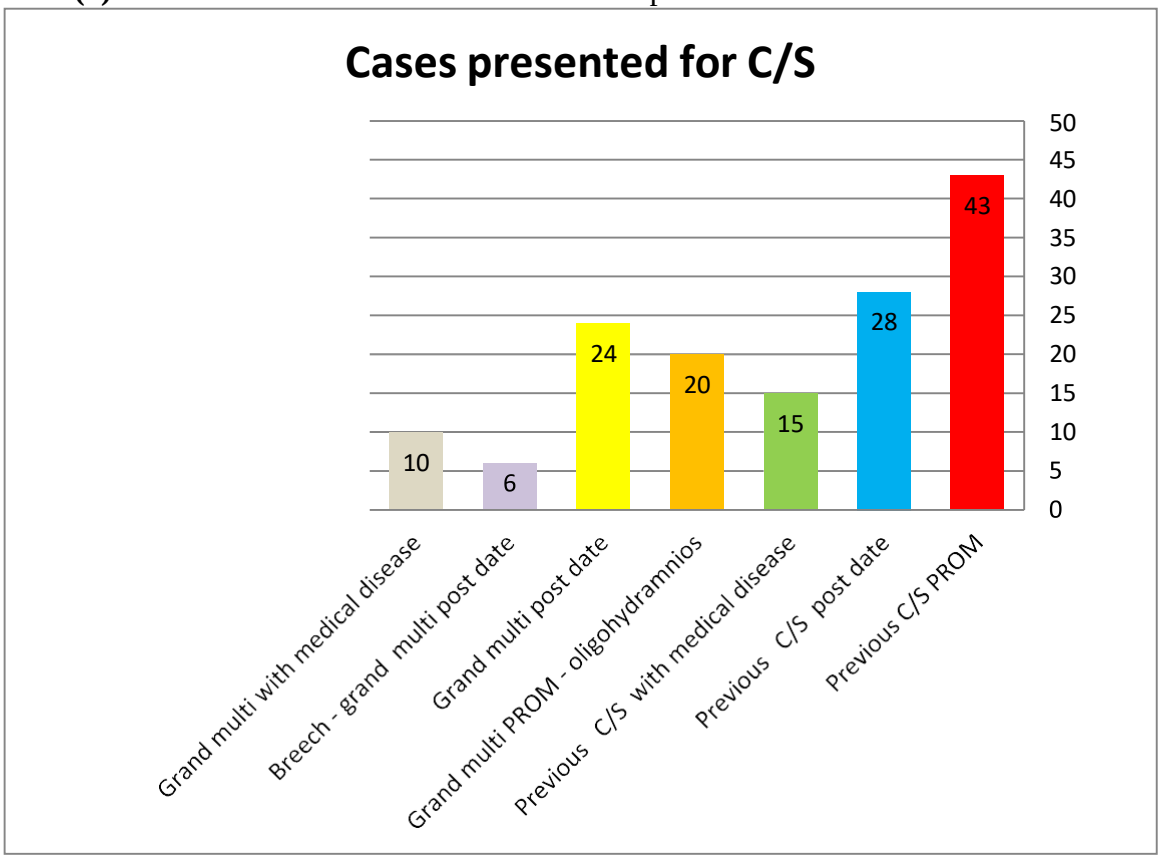

Figure (1): Cases presented for C/S

Correlations between cervical dilatation success and presented cases.

Univariate analysis revealed no significant differences between Cervical ballooning with Foley's catheter and the presented cases (Table 2).

Presented cases	Cervical ballooning with Foley's catheter		*Chi*-square test
	Normal vaginal delivery	C/S	
	Previous C/S		
PROM (43 cases)	41 (95.3%)	2 (4.7%)	
Post-date (28 cases)	26 (92.9%)	2 (7.1%)	*P*=0.00594
With medical disease (15 cases)	10 (66.7%)	5 (33.3%)	
	Grand multi		
PROM - oligohydramnios (20 cases)	19 (95%)	1 (5%)	
Breech post-date (6 cases)	3 (50%)	3(50%) (16.7%)	*P*=0.03094
With medical disease (10 cases)	7(70%)	3(30%)	

**p*-value <0.05 was statistically significant.

Table (2): Correlations between cervical dilatation success and presented cases.

Discussion

Balloon catheters were initially designed for cervical dilatation and ripening during labor induction. The best indicator of efficacy is the bishop score rise. However, when correlated with baseline data, the bishop score served only as a secondary outcome. Therefore, we could use the bishop score after catheter removal (the second Bishop score) to roughly calculate this effect size [18]. In support of this finding, Hoppe et al. [19] reported a Bishop score > 6 at balloon removal, and ripening success rates appeared to be higher. Atad et al. also reported similarly large average increments in the bishop scores for both nulliparous and multiparous women for the balloon catheter [20]. Ahmed, et al. [21] stated that women treated with a single balloon catheter had a shorter insertion to amniotomy time, while Pennell, et al. [22] and Rab, et al., [23] are preferring the single-balloon catheter. Ahmed and Mei-Dan [21, 24] suggested that the shorter interval between insertion and expulsion for the single-balloon catheter likely resulted in the observed shorter induction to delivery interval. In addition, Salim, et al. [25] found that women who spontaneously expelled their catheter demonstrated favorable outcomes with regards to shorter times from induction to delivery. The studies included Deshmukh et al, [26] Laddad et al, [27] Jozwiak et al, [28] and Al-Taani [29] reported that a shorter time to delivery was found with the use of an intracervical Foley catheter balloon. Advantages of this technique include lower cost compared with some drugs, low risk of tachysystole, few systemic side effects, and convenient storage requirements (no refrigeration or expiration, which are issues for some drugs) [30,31,32].

Limitations of the study

Our study has some limitations. First, a small sample size was used to identify the value of cervical ballooning by Foley's catheter as pre-induction for normal vaginal delivery because of the short study period. Second, there is not many studies found in our areas for comparison and discussion.

Conclusion

In conclusion, we found that cervical ballooning by Foley's catheter is a pre-induction safe method, efficient, and offering potential to increase the rate of vaginal deliveries in pregnant women with relative indication for cesarean section.

References

1. Betran AP, Ye J, Moller AB, et al. The increasing trend in caesarean section rates: global, regional and national estimates: 1990–2014. PLoS One 2016;11:e0148343.
2. Shah A, Fawole B,M'imunya JM, et al. Cesarean delivery outcomes from the WHO global survey on maternal and perinatal health in Africa. Int J Gynaecol Obstet 2009;107:191–7.
3. Villar J, Valladares E, Wojdyla D, et al. Caesarean delivery rates and pregnancy outcomes: the 2005 WHO global survey on maternal and perinatal health in Latin America. Lancet 2006;367:1819–29.
4. Lumbiganon P, Laopaiboon M, Gülmezoglu AM, et al. Method of delivery and pregnancy outcomes in Asia: the WHO global survey on maternal and perinatal health 2007–08. Lancet 2010;375:490–9.
5. Molina G, Weiser TG, Lipsitz SR, et al. Relationship between cesarean delivery rate and maternal and neonatal mortality. JAMA 2015;314:2263–70.
6. Thomas S, Meadows J, McQueen KA. Access to cesarean section will reduce maternal mortality in low-income countries: a mathematical model. World J Surg 2016;40:1537–41.
7. Ecker J. Elective cesarean delivery on maternal request. JAMA 2013;309:1930–6.
8. NIH State of the Science Conference: cesarean delivery on maternal request. Adv Neonatal Care 2006;6:171–2.
9. Jafarzadeh A, Hadavi M, Hassanshahi G, Rezaeian M, Vazirinejad R, Aminzadeh F, Sarkoohi A. Cesarean or Cesarean Epidemic? Arch Iran Med. November 2019;22(11):663-670.
10. Bayrampour H, Heaman M. Advanced maternal age and the risk of cesarean birth: a systematic review. Birth. 2010;37(3):219-26.
11. Hassain GS. Cesarean section in Babylon Province. Int J Med Sci. 2015;3(4):113-5.
12. Miller R. Miller's anesthesia. 8th ed. Philadelphia: Elsevier; 2015.
13. Mylonas I, Friese K. Indications for and risks of elective cesarean section. Dtsch Arztebl Int. 2015;112(29-30):489-95.
14. Gibbons L, Belizan JM, Lauer JA, Betrán AP, Merialdi M, Althabe F. The global numbers and costs of additionally needed and unnecessary caesarean sections performed per year: overuse as a barrier to universal coverage. World health report. Geneva: WHO; 2010.
15. Jozwiak M, Bloemenkamp KW, Kelly AJ, Mol BW, Irion O, Boulvain M. Mechanical methods for induction of labour. Cochrane Database Syst Rev. (2012, 3):CD001233.
16. ACOG Practice Bulletin No. 107: induction of labor. Obstet Gynecol 2009, 114(2 Pt 1):386–397.
17. WHO Recommendations for Induction of Labour. edn. Geneva; 2011.
18. Liu X, Wang Y, Zhang F, Zhong X, Ou R, Luo X and Qi H. Double-versus single-balloon catheters for labour induction and cervical ripening: a meta-analysis. BMC Pregnancy and Childbirth (2019) 19:358.

19. Hoppe KK, Schiff MA, Peterson SE, Gravett MG. 30 mL single- versus 80 mL double-balloon catheter for pre-induction cervical ripening: a randomized controlled trial. J Matern Fetal Neonatal Med. 2016;29(12):1919–25.
20. Atad J, Bornstein J, Calderon I, Petrikovsky BM, Sorokin Y, Abramovici H. Nonpharmaceutical ripening of the unfavorable cervix and induction of labor by a novel double balloon device. Obstet Gynecol. 1991;77(1):146–52.
21. Sayed Ahmed WA, Ibrahim ZM, Ashor OE, Mohamed ML, Ahmed MR, Elshahat AM. Use of the Foley catheter versus a double balloon cervical ripening catheter in pre-induction cervical ripening in postdate primigravidae. J Obstet Gynaecol Res. 2016;42(11):1489–94.
22. Pennell CE, Henderson JJ, O'Neill MJ, McChlery S, Doherty DA, Dickinson JE. Induction of labour in nulliparous women with an unfavourable cervix: a randomised controlled trial comparing double and single balloon catheters and PGE2 gel. BJOG. 2009;116(11):1443–52.
23. Rab MT, Mohammed AB, Zahran KA, Hassan MM, Eldeen AR, Ebrahim EM, Yehia M. Transcervical Foley's catheter versus Cook balloon for cervical ripening in stillbirth with a scarred uterus: a randomized controlled trial. J Matern Fetal Neonatal Med. 2015;28(10):1181–5.
24. Mei-Dan E, Walfisch A, Suarez-Easton S, Hallak M. Comparison of two mechanical devices for cervical ripening: a prospective quasi-randomized trial. J Matern Fetal Neonatal Med. 2012;25(6):723–7.
25. Salim R, Zafran N, Nachum Z, Garmi G, Kraiem N, Shalev E. Single-balloon compared with double-balloon catheters for induction of labor: a randomized controlled trial. Obstet Gynecol. 2011;118(1):79–86.
26. Deshmukh VL, Yelikar KA, Deshmukh AB. Study of intra-cervical Foley's catheter and PGE2 gel. J Obstet Gynecol India 2011;61:418–21.
27. Laddad MM, Kshirsagar NS, Karale AV. A prospective randomized comparative study of intra-cervical Foley's catheter insertion versus PGE2 gel for pre-induction cervical ripening. Int J Reprod Contracept Obstet Gynecol 2013;2:217–20.
28. Jozwiak M, Oude Rengerink K, Benthem M, et al. Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT Trial): An open-label, randomised controlled trial. Lancet 2011;378:2095–103.
29. Al-Taani MI. Comparison of prostaglandin E2 tablets or Foley catheter for labour induction in grand multiparas. East Med Health J 2004;10:547–53.
30. Du YM, Zhu LY, Cui LN, Jin BH, Ou JL. Double-balloon catheter versus prostaglandin E2 for cervical ripening and labor induction: a systematic review and meta-analysis of randomized controlled trials. BJOG. 2016 Aug 17.
31. Alfirevic Z, Keeney E, Dowswell T, Welton NJ, Medley N, Dias S. Methods to induce labour: a systematic review, network meta-analysis and cost-effectiveness analysis. BJOG. 2016;123 (9):1462-70.
32. Durie D, Lawal A, Zegelbone P. Other mechanical methods for pre-induction cervical ripening. Semin Perinatol. 2015;396:444-9.