# Journal of Medical Ethics and History of Medicine



## Balloon Dilators for Labor Induction: a Historical Review

### James Andrew Smith<sup>1</sup>

<sup>1</sup> Assistant Professor, Department of Electrical & Computer Engineering, Ryerson University, Toronto, Canada

*Corresponding Author:* Jaes Andrew Smith Address: Department of Electrical and Computer Engineering, Ryerson University 350 Victoria St. Toronto, ON, M5B 2K3 Canada Email: jasmith@ee.ryerson.ca Tel: 416-979-5000 Fax: 416-979-5280

Received: 05 Apr 2013 Accepted: 26 Oct 2013 Published: 3 Nov 2013

J Med Ethics Hist Med, 2013, 6:10 © 2013 James Andrew Smith.; license Tehran Univ. Med. Sci.

#### Abstract

A number of recent articles attribute the origin of the use of cervical balloon dilation in the induction of labor to either Barnes in the 1860s or Embrey and Mollison in the 1960s. This review examines the historical record and reveals that, based on current practice attribution should rather be made to two contemporaries of Barnes: the Storer and Mattei. More importantly, Storer's warning about the rubber used in dilators was ignored, leading to decades of possibly unnecessary deaths following childbirth. To conduct this study key search terms for PubMed, Google Scholar and the website of the University of Ryerson were utilized as "Barnes", "Woodman", "balloon dilation", "balloon catheter", "foley", "colpeurynter", "cervix uteri" and "induction." Subsequent analysis was done on downloaded articles using BibDesk.

Keywords: balloon dilation, cervical dilation, foley catheter, hydrostatic dilator, induction of labor

#### Introduction

The use of balloons for dilation is widespread in contemporary medical practice, including in obstetrics and gynecology, dilatation and curettage, induction of labor, control of hemorrhaging, sonohysterography and hysterosalpingography, and fertility treatment. The scope of this analysis will be limited to the use of balloon dilators in induction of labor. The goal of this review is to point out inaccurate attribution of prior art, specifically the tendency of contemporary authors to attribute the origin of cervical balloon dilation in the induction of labor to either Barnes in the 1860s (1) or Embrey and Mollison in the 1960s (2). Had Barnes and others paid closer attention to Storer's earlier balloon dilator work (3), which raised the issue of rubber's biocompatibility risks, the infection and mortality rate during labor from the 1860s onward may have been reduced.

#### **Survey of the Literature**

In 1591 Alpinus described how air could be used to inflate distensible material in the urethra (4). Later, Bromfeild used liquid-based distention of animal intestine to remove stones in a girl's bladder (5). Animal-sourced balloon dilators were replaced with vulcanized rubber by the 1850s. The new material could be more easily cleaned prior to usage, although it carried similar risks of bursting and leaking.

In 1854 Gariel described balloon dilator designs for the cervix (6), but no medical interventions using these devices were published. It was reported in 1855 that Braun had used water-distended rubber balloons to dilate the cervix (7). Braun applied his colpeurynter during a labor that had already commenced but was complicated by the presenting of the baby's shoulder.

Mattei detailed use of a rehydrated sheep's bladder design to dilate the cervix during labor in patients in 1855 as an alternative to digital dilation. Mattei suggested that the ideal placement of the balloon was within the uterus and that traction should be applied to dilate the cervix. Like Braun, this method was applied to labor which had already commenced and the procedure lasted only a few minutes (8).

In 1859 a controversy began when Murray claimed to have used a rubber-based air-distended dilator to induce labor (6). It was immediately recognized that Murray's work was too closely tied to his supervisor, Keiller, to consider it Murray's own unique accomplishment (9). Storer, in response to Murray, made a claim (3) for the use of a balloon dilator for the induction of labor. Storer observed that vulcanized rubber was bulky and apt to break down after contact with bodily fluids (10), opting for the more hygienic gold-beater's skin, a

material commonly used for condoms. Unlike Keiller and Murray, Storer used water to distend the balloon. Barnes (11) and Tarnier (12) improved on these earlier designs which were subsequently well received (1, 13), even though they broke down (14) or burst (15). Tarnier's device spawned both the Boissard and Voorhees designs (15, 16). By the early 20th century warnings were raised about the Voorhees design (17) and alternatives (18), and it was concluded that they were not optimal for induction of labor (18).

The decline of the invasive and infection-prone balloon corresponds to the ascension of pharmacological alternatives from ergot to oxytocin and prostaglandins. Embrey and Mollison's use of the foley catheter reintroduced the medical community to induction balloons (2). The foley is the most commonly used balloon dilator (19) but there are alternatives (20).

#### Analysis

While Barnes first published results seven years after Mattei, his name quickly became synonymous with the balloon dilator. Woodman criticized Tarnier for not citing Barnes' earlier work but did not cite any of Barnes' predecessors either (1). Likewise, Corner made no mention of Barnes' predecessors (13). The deferral to Barnes is possibly due to his standing within the medical community (13, 21). More recently, Embrey and Mollison, as well as Calder glossed over historical prior art (2, 22). Further issues regarding addressing of prior art are expanded upon below.

Oversights in the Historical Record

Many historical examinations of balloons for labor induction go no further than Embrey and Mollison, either limiting the scope to the foley instantiation (23) or mistakenly limiting any balloon-based cervical ripening to them (24). Bani-Irshaid et. al wrongly attribute use of the foley catheter to Krause in 1833 – one hundred years before its actual invention (25, 26). While Embrey and Mollison were the first to use one particular instantiation of a balloon catheter, the foley, they were not the first to use balloons.

The following are very clear-cut cases in which attribution is incorrect. Lurie and Rabinerson misstated Barnes' role in 1997 (27). Similarly Mozurkewich (28) and Guinn et al. attribute the balloon's origin to Barnes (29, 30). Pettker et al. also wrongly refer to Barnes as the first implementer (31). Williamson mistakenly advanced the introduction of Barnes' fiddle-shaped dilator to 1852 (32), eight years earlier than Barnes admits to in any of his own publications.

Other works overlook important contributions by some of the main players in the 1859 controver-

sy related to Murray's original publication. Hibbard makes mention of both Barnes and Murray but neither Keiller nor Storer (33). Duchatel ignores the 1859 controversy but cites relevant and important work by Mattei (16).

Credit should be attributed to the design which bears the critical design and application features which are used today: a relatively hygienic material, distention with water, dilation of the cervix using pressure from above, and application to the induction of labor.

Mattei used dehydrated sheep's bladders because of convenience, not hygiene. Storer made it clear that vulcanized rubber was a poor choice for dilation due to its propensity for breaking down after contact with bodily fluids. In the long term, it appears that while the balloons were mechanically effective, they carried a hygienic risk, which led most practitioners to abandon them prior to Embrey and Mollison's reintroduction. Storer was correct in his concerns about vulcanized rubber but it is difficult to know if, had others used goldbeater's skin, the outcome would have been different prior to the introduction of latex.

The issue of water distention is an important one. Bromfeild described water-based urethral dilation in 1773 (5). Air-based techniques were later proposed by Gariel (34) and implemented by Keiller and Murray (9). Barnes, a strong fluid distention advocate, wrongly attributed Murray (and, by extension, Keiller) as the first to have used fluid to distend a cervical dilator balloon (35) as Murray specifically states that he used air to distend his air pessary in 1859. It was Storer rather who correctly applied fluid (i.e. liquid) rather that the more dangerous air alternative (10), just as today it is standard practice to use saline solution to distend the foley during induction.

Embrey and Mollison were not the first to place their balloon dilator in or against the interior os of

the cervix, as is common practice today (36). Both Mattei and Storer advocated for the "from above downwards" (10) approach to dilating the cervix, as opposed to applying force from the vagina upwards or radially within the cervix itself.

Judging by today's standards, the waterdistended balloon dilators of both Mattei and Storer appear to be the forebears of the contemporary foley dilator. Storer's approach, however, was perhaps more hygienic than Mattei's sheep's bladder or the vulcanized rubber used by Barnes and others.

#### Conclusion

This review examined the historical record related to the development of balloon dilators, specifically those used in dilation of the cervix to induce labor. While some attribute invention of the contemporary hydrostatic dilators such as the foley catheter to either Embrey or Mollison in the 1960s or to Barnes one century prior, credit should be partially given to Keiller and Murray for their approach which was nearly completely correct, except for their use of air. However, both Mattei and Storer applied liquid-based distention in a downwards manner prior to Barnes' first published results. Storer's results stand out for his hygienic concerns. Had Barnes and others paid closer attention to Storer's earlier work, subsequent infection and mortality rates may have been reduced.

#### Acknowledgment

The author would like to thank Donald Smith for proofreading the document. The author states that he has no financial conflict of interest or other interests that influence this manuscript.

#### References

- 1. Woodman WB. Induction of labour at the eighth month, and delivery of a living child in less than four hours by Dr. Barnes's Method. Lancet 1863; 81(2053):10–11.
- 2. Embrey MP, Mollison BG. The unfavorable cervix and induction of labour using a cervical balloon. Int J Obstet Gynaec 1967; 74(1): 44–48.
- 3. Storer HR. On an uterine dilator. Med Times Gazette 1859; 19: 388.
- 4. Alpin P. La Médecine des Egyptiens, vol. 1. La Collection des Voyageurs Occidentaux en Egypte. Paris: Institut français d'Archéologie Orientale; 1980. [in French]
- 5. Bromfeild W. Chirurgical Observations and Cases. England: T. Cadell; 1773.
- 6. Murray JJ. Placenta Praevia air-Pessary used to plug and dilate the Os uteri. Med Times Gazette 1859; 18: 596 7.
- 7. Chiari J, Braun C, Spaeth J. Klinik der Geburtshilfe und Gynaekologie. Ealangen: Verlag von Ferdinand Enke; 1855. [In German]
- 8. Mattei A. Essai sur l'accouchement physiologique. Paris: Victor Masson; 1855. [in French]
- 9. Keiller A. Air-dilators and plugs in obstetrics practice. Med Times Gazette 1859; 18: 639.
- 10. Storer HR. The uterine dilator. Am J Med Sci 1859; 38(75):107-113.
- 11. Barnes R, Barnes F. A system of obstetric medicine and surgery: theoretical and clinical. London: Smith, Elder & Co; 1885, vol 2.

- 12. Galante H. De l'emploi du caoutchouc vulcanisé dans la thérapeutique médico-chirurgicale. Paris: Bailliere; 1869. [In French]
- 13. Corner FM. On a case of induction of premature labour by Dr. Barnes's method. Lancet 1863; 81(2057):115–16.
- 14. Joulin M. Traité complet d'accouchements. Paris: F. Savy; 1867. [In French]
- 15. Veyre JF, Laumosne J, Mavel A, Feldman JP, Pelikan P, Michiels Y. Le ballon de Boissard: antiquité ou moyen moderne de déclenchement. Rev Franç Gynéc1974; 69(10): 535–9. [In French]
- 16. Duchatel F. Evolution des méthodes actuelles de déclenchement du travail. Hist Sci Méd 1996; 30(2): 251-7. [In French]
- 17. Madden AL. The voorhees bag in the induction of labor, a criticism. Am J Obstet Gynecol 1926; 12: 875–9.
- 18. Waters EG. The dilating bag in obstetrics. Its use, abuse and hazards. Am J Obstet Gynecol 1938; 36(4): 639–47.
- 19. Moleti CA. Trends and controversies in labor Induction. MCN Am J Matern Child Nurs 2009; 34(1): 40-7.
- 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. Anonymous. Robert Barnes, M.D. (obituary). BJOG 1907; 11(6): 519-522.
- 22. Calder AA. Cervical ripening; physiology and therapy. J Obstet Gynaecol 1988; 8(s1): S2–S6.
- 23. Sherman DJ, Frenkel E, Tovbin J, Arieli S, Caspi E, Bukovsky I. Ripening of the unfavorable cervix with extraamniotic catheter balloon: clinical experience and review. Obstet Gynecol Surv 1996; 51(10): 621–7.
- 24. Lewis S, Collins M. Induction of Vaginal Birth After Cesarean Using Intracervical Foley Bulb. J Midwifery Womens Health 2008; 53(6): 565–6.
- 25. Foley FEB. A hemostatic bag catheter a one piece latex rubber structure for control of bleeding and constant drainage following prostatic resection. J Urol 1937; 38(1):134–139.
- 26. Bani-Irshaid I, Athanneh TZ, Bani-Khaled D, Al-Momani M, Dahamsheh H. Termination of second and early third trimester pregnancy: comparison of 3 methods. East Mediterr Health J 2006; 12(5): 605–9.
- 27. Lurie S, Rabinerson D. Balloon ripening of the cervix. Lancet 1997; 349(9050): 509.
- 28. Mozurkewich E. Commentary on Foley catheter insertion for preinduction cervical ripening was faster and more efficacious than prostaglandin E<sub>2</sub> gel. Evidence-based Obstet Gynaecol 2000; 2(2): 41.
- 29. Guinn DA, Goepfert AR, Christine M, Owen J, Hauth JC. Extra-amniotic saline, laminaria, or prostaglandin E(2) gel for labor induction with unfavorable cervix: a randomized controlled trial. Obstet Gynecol 2000; 96(1): 106–12.
- 30. Guinn DA, Davies JK, Jones RO, Sullivan L, Wolf D. Labor induction in women with an unfavorable Bishop score: randomized controlled trial of intrauterine Foley catheter with concurrent oxytocin infusion versus Foley catheter with extra-amniotic saline infusion with concurrent oxytocin infusion. Am J Obstet Gynecol 2004; 191(1): 225–9.
- 31. Pettker CM, Pocock SB, Smok DP, Lee SM, Devine PC. Transcervical Foley catheter with and without oxytocin for cervical ripening: a randomized controlled trial. Obstet Gynecol 2008; 111(6): 1320–6.
- 32. Williamson H. The induction of premature labour. J Obstet Gynaecol 1905; 8(4): 252-71.
- 33. Hibbard BM. The obstetrician's armamentarium: historical obstetric instruments and their inventors. California: Norman Publishing; 2000.
- 34. Gariel MM. Medico-Chirugical Uses of Vulcanised India-Rubber. Translated by Murray JJ. Medical Times and Gazette1859; 40(1033 (New Series No 472): 64–66.
- 35. Barnes R. On the indications and operations for the induction of premature labour and for the acceleration of labour. In Obstetrical Society of London, Transactions of the Obstetrical Society of London. Longmans, Green and Co; 1861; 3:107-141.
- 36. Tenore JL. Methods for cervical ripening and induction of labor. Am Fam Physician 2003; 67(10): 2123-8.