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Randomised Italian Sonography for occiput POSition Trial Ante vacuum (R.I.S.POS.T.A.)

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ABSTRACT

Objective *To assess whether sonographic diagnosis of fetal head position before instrumental vaginal delivery can reduce the risk of failed vacuum extraction and improve delivery outcome.*

Methods *Randomised Italian Sonography for occiput POSition Trial Ante vacuum (R.I.S.POS.T.A.) is a randomized controlled trial of term (37 + 0 to 41 + 6 weeks' gestation) singleton pregnancies with cephalic presentation requiring instrumental delivery by vacuum extraction, which was conducted between April 2014 and June 2017 and involved 13 Italian maternity hospitals. Patients were randomized to assessment of fetal head position before attempted instrumental delivery by either vaginal examination (VE) alone or VE plus transabdominal sonography (TAS). Primary outcome was incidence of emergency Cesarean section due to failed vacuum extraction. A sample size of 653 women per group was planned to compare the primary outcome between the two groups. The sample size estimation was based on the hypothesis that the risk of failed vacuum delivery in the VE group would be 5% and that ultrasound assessment of fetal position prior to vacuum extraction would decrease this risk to 2%.*

Results *On interim analysis, the trial was stopped for futility. During this period, 222 women were randomized and 221 were included in the final data analysis, of whom 132 (59.7%) were randomized to evaluation of fetal head position by VE only and 89 (40.3%) to assessment by VE plus TAS prior to vacuum extraction. No significant differences were observed between the two groups with respect to incidence of emergency Cesarean section due to failed instrumental delivery and other maternal and fetal outcomes. Women randomized to assessment by VE plus TAS showed higher incidence of non-occiput anterior position of the fetal head at randomization and lower incidence of incorrect diagnosis of occiput position compared with women undergoing assessment by VE alone. A higher rate of episiotomy was noted in the women undergoing both VE and TAS compared with those in the VE-only group.*

Conclusions *Our prematurely discontinued randomized controlled trial did not demonstrate any benefit in terms of reduced risk of failed instrumental delivery or maternal and fetal morbidity in women undergoing sonographic assessment of fetal head position prior to vacuum extraction. Copyright © 2018 ISUOG. Published by John Wiley & Sons Ltd.*

INTRODUCTION

Instrumental vaginal delivery by vacuum extraction is a widely performed obstetric procedure[1,2] used to expedite delivery when there is substantial risk for the mother or fetus during the second stage of labor. Although successful in most cases, a 4–6% failure rate has been reported following attempted vacuum delivery[3–5]. Cesarean section and sequential instrumental delivery with forceps are the available options to achieve delivery of the fetus after failure of vacuum extraction, but increased risk of maternal and fetal complications has been reported in such cases[5,6].

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