Antenatal use of a novel vaginal birth training device by term primiparous women in Singapore

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ABSTRACT

Introduction: **To study the use, safety and effectiveness of a novel antenatal vaginal birth training device (EPI-NO®) in primiparous women.**

Methods: **Antenatal use of the EPI-NO® vaginal birth trainer was prospectively studied in 31 primiparous booked patients who were delivered by obstetricians from July to December 2002 at the KK Women's and Children's Hospital. This was studied in relation to episiotomy rate, perineal trauma and analgesic requirements during the postpartum period. A patient questionnaire form was used to assess their perception of pain and how well they coped with its use. For comparison, perineal trauma was also studied retrospectively in 60 consecutive obstetrician-booked primiparous term patients who had normal vaginal delivery (NVD) and who did not use EPI-NO® during the same study period.**

Results: **The mean length of usage was for 2.1 weeks (standard deviation [sd] 1.2 weeks). The mean frequency of use was 5.3 episodes per week (sd 2.1, range 1 to 7). There was no laceration and vaginal infection arising from its usage. There was a case of minimal bleeding post-usage. There were 20 (64.5 percent) NVDs, four (12.9 percent) forceps deliveries, five vacuum deliveries (16.1 percent) and two (6.5 percent) Caesarean sections. Of the 29 vaginal delivery cases, 19 (65.5 percent) had episiotomy, eight (27.6 percent) had lacerations, and two (6.9 percent) did not sustain laceration. The reasons for episiotomy in the 19 cases were nine cases of pending tearing of vagina/perineum, nine cases of instrumental vaginal deliveries, and one to shorten second stage. There was no third degree tear. 21 (67.7 percent) out of 30 required a painkiller. The majority of patients (17; 54.8 percent) appeared to be comfortable with the use of EPI-NO®. All coped well with vaginal examination after using EPI-NO® perineal training. Comparing among term primiparous NVD cases with (n value equals 20) and without (n value equals 60) EPI-NO®, the perineal trauma rate (90.0 percent vs 96.6 percent, p value equals 0.24) was slightly but not significantly lower in the EPI-NO® group. The episiotomy rate was significantly lower (50.0 percent vs 93.3 percent, p value is less than 0.0001) and the extent of perineal trauma in the patient appeared to be less severe in cases using EPI-NO®.**

Conclusion: **EPI-NO® appeared to be safe and acceptable to the majority of users. Although birth training with EPI-NO® significantly decreases the rate of episiotomies in term primiparous patients, and the degree of perineal tissue injury appeared to be less in the EPI-NO® group especially among those with lacerations, the overall perineal trauma rate was slightly but not significantly lower, in view of the higher spontaneous laceration rate in the EPI-NO® group.**

Keywords: EPI-NO vaginal birth trainer, episiotomy, perineal tissue injury, perineal trauma, vaginal delivery

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INTRODUCTION

Perineal trauma is an important aspect of childbirth that can affect women in labour. Perineal trauma can occur either from spontaneous lacerations or episiotomy. Spontaneous laceration is defined as a tear of the perineal tissue sustained during childbirth, whereas episiotomy is the surgical enlargement of the vaginal orifice by an incision of the perineum during the last part of the second stage of labour or delivery. This procedure is done with scissors or scalpel and requires repair by suturing. The purpose of episiotomy has been to facilitate delivery for mother and child, to make delivery shorter, and to prevent extension of perineal lacerations. Many accouchers felt that episiotomy being a clean cut was also easier to repair. Episiotomy evidently reduces the risk of anterior perineal tears[1].

The rate of episiotomy has risen considerably and it now ranked as the most frequent surgical operation

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on women worldwide. The rate differs from country to country and from institution to institution[2-6]. In Singapore, episiotomy seems to be almost routine for the local primiparous term patients.

However, evidence in the published literature indicates that the liberal or routine use of episiotomy may do more harm than good[1,7]. The restrictive use of episiotomy shows a lower risk of posterior perineal trauma, need for suturing perineal trauma, and healing complications at seven days[1]. Indications for routine episiotomy are thus not well supported. The knowledge of these negative and unpleasant effects for patients makes it appropriate and justified to search for methods to reduce the rate of episiotomy and tears of the perineum and to improve the birth outcomes for women. The aim was to study the antenatal use of EPI-NO® in term primiparous patients in relation to episiotomy rate, perineal tear rate, analgesic requirements during postpartum period and other obstetric outcomes.

METHODS

Antenatal use of the EPI-NO® vaginal birth trainer was prospectively studied in 32 primiparous patients booked with and delivered by obstetricians at the KK Women's and Children's Hospital (KKH) from July to December 2002. This was undertaken in the setting where episiotomy appeared to be performed routinely for primiparous term patients during vaginal delivery. KKH is the largest maternity unit in Singapore and there were 14,837 deliveries in 2002. Private patients booked under the care of obstetricians and attending antenatal classes in KKH were asked whether they would be interested in taking part in the study. Informed written consent was undertaken. They were instructed on the use the EPI-NO® device generally starting at 37 weeks, and up to a maximum of 15 minutes per day till delivery. Instructions were provided with an information leaflet. The women were asked to keep a log so that the frequency and duration of EPI-NO® practice can be documented. They were also asked to report any problems or complications relating to its use.

The inclusion criteria were primiparae (no previous vaginal delivery) and single pregnancy. The exclusion criteria were multiparae, multiple pregnancy, previous vaginal/perineal surgery, uncertain dates, medical complications, and estimated foetal birth weight by ultrasonography greater than 4000gms. The discontinuation criteria were any time the woman felt uncomfortable and wanted to discontinue, any suspicion of vaginal infection, and any significant episode of post-use bleeding. Allergy to rubber as a possible side effect was advised. Instructions were given to patients as to how to use the device. The main aim of using this device was to stretch the perineal muscle in the antenatal period. This study involved the patient self-introducing EPI-NO® device into the vagina at around 37th week of gestation and to pump up the pressure in the balloon to slowly stretch the vulva, the perineum and the vaginal muscle.

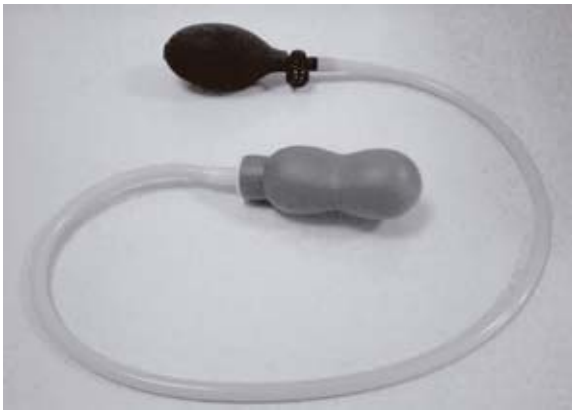

Fig. 1 Photograph of the EPI-NO® vaginal birth trainer.

Fig. 2 Photograph of the EPI-NO® vaginal birth trainer with pressure gauge.

The EPI-NO® birth trainer consists of an inflatable silicone balloon connected to a hand pump. There are two types: with and without the pressure gauge (Figs. 1 & 2). The EPI-NO® has been available in Germany since October 1999 and appears to be the only device of this kind on the market at the time of writing. The birth trainer consists of an inflatable balloon which is designed to dilate the vagina with the aim of gradually adapting the vagina and perineum to greater penetration volumes, to train a feeling of sufficient pressing and hopefully, to decrease the rate of episiotomies during delivery. The balloon needs to be pumped up so that it becomes firm and facilitates its introduction into the vagina. A lubricant is used which can be either vaseline or a lubricant gel. The balloon is fed with a rotating movement into the vagina so that it is still visible about 2cm in front of the vagina. The balloon is then held in this position

Appendix I. Patient questionnaire for pain assessment.

Please circle the answer which described your feelings most appropriately.

1) Please rate the pain you felt at the perineum at the end of delivery

0 1 2 3 4 5 6 7 8 9 10

(No pain) (Most severe pain)

2) Please rate the pain you felt at the perineum at the first day after your delivery

0 1 2 3 4 5 6 7 8 9 10

(No pain) (Most severe pain)

3) Please rate the pain you felt at the perineum at the 3rd day after your delivery

0 1 2 3 4 5 6 7 8 9 10

(No pain) (Most severe pain)

4) Please rate the pain you felt at the perineum at the 7th day after your delivery

0 1 2 3 4 5 6 7 8 9 10

(No pain) (Most severe pain)

5) Did you need to take painkillers for your perineal pain?

❒ Yes

❒ No

6) When did you stop taking the painkillers for your perineal pain?

Day of delivery _____

with the left hand between the index and middle finger while the balloon is pumped up with the right hand in steps. The pregnant mother is advised to stop at any time she feels uncomfortable. Once the balloon is blown up, the pregnant mother tries to control the gliding balloon with her vaginal muscles in order to simulate childbirth. This can be assisted in the beginning by gently leading the balloon out with the hand. After some attempts, this should be restarted with the balloon deflated and then pumped up again with the exercise continuing. This is continued for 15 minutes each day for 14 days from 36 to 38 weeks. The threshold of pain must not be exceeded under any circumstances. After use, the balloon is washed with soap and water, and dried.

During the second stage of labour, the accouchers were requested to refrain from routinely performing an episiotomy, unless deemed necessary, for patients in this study project. After the delivery, a form on lacerations/episiotomy, if any, was completed by the accoucher. This form was mainly to note the outcome of the perineum. A patient questionnaire was used to rate the pain they felt at the perineum at the end of delivery, and on the 1st, 3rd and 7th days after the delivery. The form also inquired on the need to take painkillers for any perineal pain and the day on which they stop taking the painkillers for the perineal pain (Appendix I). One of the investigators (PSC) conducted follow-up with telephone calls if the patient had been discharged from the hospital to obtain the pain score. She also asked about the comfort level in using EPI-NO® and whether they coped well with vaginal examination after using EPI-NO® at the first phone call. On a subjective scale relating to fear of using EPI-NO® (0 for no fear and 10 for very fearful), the patients were asked to describe the level of fear, if any, when using the device. A score of four or less was considered as being desirable. On a subjective scale relating to comfort in using EPI-NO® (0 for very comfortable and 10 for very uncomfortable), they were also describe their comfort level in using the device, with a score of four or less considered as being desirable.

Perineal trauma was also studied retrospectively in 60 consecutive primiparous term private patients booked under the care of obstetricians who had normal vaginal delivery and who did not use EPI-NO® during the same study period. They served

as the control group when comparing with the EPI-NO® group who had normal vaginal delivery. Statistical analysis was performed using the SPSS Software version 10. Statistical analyses were performed using chi-square test for categorical variables and unpaired t-test for continuous variables.

RESULTS

A total of 31 primiparous term patients were recruited. The mean age was 31.1 years (standard deviation [sd] 3.1, with range from 26 to 40 years). There were 25 (80.6%) Chinese, two (6.5%) Malay, one (3.2) Indian and three (9.7%) other races. The majority (58.1%, 18 cases) of the initiation of the usage was at 37 weeks gestation, followed by eight (25.8%) at 36 weeks, three (9.7%) at 38 weeks, and two (6.5%) at 39 weeks. The mean length of usage was for 2.1 weeks (sd 1.2 weeks), ranging from less than one week to up to four weeks. The mean frequency of use per week was 5.3 episodes (sd 2.1, with range from 1 to 7). 15 (48.4%) patients had used EPI-NO® daily. The duration of application ranged from 1 minute to 20 minutes, with most (nine cases, 29.0%) using it for 10 minutes. There was no laceration and vaginal infection arising from its usage. There was a case of minimal bleeding post-usage.

There were 20 (64.5%) normal vaginal deliveries, four (12.9%) forceps deliveries, five vacuum deliveries (16.1%) and two (6.5%) Caesarean sections. One Caesarean section was for breech presentation and the other was for cephalopelvic disproportion in labour. The mean gestation at delivery was 39.0 weeks (sd 0.9, with range from 37 to 40 weeks). 16 (51.6%) patients were solely on epidural anaesthesia, two (6.5%) on pethidine, nine (29.0%) on entonox, two (6.5%) were on both pethidine and entonox, two (6.5%) were on epidural anaesthesia and entonox, and one (3.2%) was on pethidine, epidural anaesthesia and entonox. The mean baby weight was 3177g (sd 416g), with range from 2470g to 4255g.

Length of the second stage ranged from 7 to 203 minutes for 30 patients, with a mean of 83.3 minutes (sd 60.7 minutes). Duration of active pushing ranged from 7 to 114 minutes, with mean of 55.2 minutes (sd 34.1 minutes). The position of the head in labour was documented in 28 cases (eight left occipital anterior, four right occipital anterior, 10 left occipital transverse, four right occipital transverse, one direct occipital posterior and one left occipital posterior). The position of the head at delivery was also documented in 28 cases (19 left occipital anterior and nine right occipital anterior).

Of the 29 vaginal delivery cases, 19 (65.5%) had episiotomy, eight (27.6%) had lacerations and two (6.9%) did not sustain laceration. The reasons for episiotomy in the 19 cases were nine cases of "pending tearing of vagina/perineum", nine cases of instrumental vaginal deliveries, and one to shorten the second stage. 14 (73.7%) out of the 19 episiotomy cases had extended tears and all 19 were second degree tears. Among the 10 cases without episiotomy, there was only one case of multiple tears which were superficial and measured 0.5cm in length. Three out of the 11 cases without episiotomy were first degree tears, and the rest were second degree tears. The mean length of episiotomy was 3.4cm (sd 1cm, range 1.5cm to 5cm). The mean length of tear (for the eight cases with lacerations) was 2.4cm (sd 1.1cm, range 1cm to 4cm). There was no third degree tear. All the nine instrumental vaginal deliveries cases had episiotomy. Six (66.7%) out of the nine cases had extended tears, and all nine were second degree tears. The mean length of episiotomy of the 10 cases was 4cm (sd 0.9cm, range 3cm to 5cm).

Analysing the subgroup of the 20 normal vaginal delivery cases (excluding instrumental deliveries), 10 (50.0%) had episiotomy, eight (40.0%) had lacerations, and two (10.0%) did not sustain any trauma. Eight (80.0%) out of the 10 episiotomy cases had extended tears, and all 10 were second degree tears. Among the 10 cases without episiotomy, there was a case of multiple tears which were superficial and measured 0.5cm in length. Three (37.5%) out of the eight cases with lacerations were first degree tears, and the rest were second degree tears. The mean length of episiotomy of the 10 cases was 3cm (sd 0.8cm, range 1.5cm to 4cm), and was longer than the mean length of tear (for the eight cases with spontaneous lacerations) which was 2.4cm (sd 1.1cm, range 1cm to 4cm). This difference was however not statistically significant.

For the group of 60 consecutive normal vaginal deliveries with no EPI-NO® usage during the same study period matched for term and primiparity, retrospectively, and who were booked and delivered by obstetricians, 56 (93.3%) had episiotomy, two (3.3%) had laceration, and two (3.3%) did not sustain any trauma. There was one case of third degree tear involving the anal sphincter, and the rest were second degree tears. One case had significant multiple tears recorded. Comparing among term primiparous normal vaginal deliveries cases with (n=20) and without (n=60) EPI-NO®, although the episiotomy rate was significantly lower (50.0% vs 93.3%, $p<0.0001$), the perineal trauma rate (90.0% vs 96.6%, $p=0.24$) was slightly but not significantly lower.

21 (67.7%) out of 30 patients required a painkiller. On a subjective scale of pain (0 for no pain and 10

for most severe pain), the mean pain scores at end of delivery, 1st day, 3rd day and 7th day were 2.2 (sd 1.9), 3.5 (sd 1.9), 3.1 (sd 2.1) and 1.6 (sd 1.9), respectively. The mean number of day at which pain killer were stopped was 4.6 (2.2) days. On a subjective scale relating to fear of using EPI-NO® (0 for no fear and 10 for very fearful), 21 (67.7%) had a score of 4 or less. On a subjective scale relating to comfort in using EPI-NO® (0 for very comfortable and 10 for very uncomfortable), 17 (54.8%) had a score of 4 or less. All (100%) reported that they coped well with vaginal examination after perineal training using EPI-NO®.

DISCUSSION

A number of antenatal measures have been developed to reduce episiotomies and improve perineal outcome in vaginal deliveries. This include perineal massage[8-10] and recently, the use of a vagina birth trainer device[11]. Shipman et al[8] showed that antenatal perineal massage appeared to have some benefit in reducing second or third degree tears or episiotomies and instrumental deliveries, while Labrecque et al[9] reported that antenatal perineal massage was an effective approach to increasing the chance of delivery with an intact perineum for women with a first vaginal delivery but not for women with a previous vaginal birth. However, Stamp et al[10] showed that perineal massage in the second stage of labour (intrapartum) did not have any effect on the likelihood of an intact perineum, perineal trauma, pain, or subsequent sexual, urinary or faecal outcomes but was not harmful.

At the time of writing, only one German study by Hillebrenner et al[11] on the use of the antenatal vaginal birth trainer has been published. Hillebrenner et al showed, in the comparison of 45 primiparous term matched-pairs, that the episiotomy rates of the women in the control group who delivered with episiotomy was 82% compared to only 49% in the EPI-NO® birth trainer group. This was statistically significant. Perineal tears of first and second degrees were also lower but not statistically significant in the EPI-NO® group (2%), in comparison to 4% in the control group

This is the first study reporting on the antenatal use of a vaginal birth training device in Singapore and in Asia. Asian women, being smaller-built, may have different outcomes, especially if staying in affluent cities where increasing trends of obesity and diabetes may lead to bigger babies. As it involves inserting a device to vagina, it would be expected that many local Asian antenatal patients would have some reservations. However, this study showed that it appeared to be acceptable and safe to our local patients. An advantage would be that it helped the labouring patient cope with vaginal examinations. All patients in this study reported that they coped well with vaginal examination after perineal training using EPI-NO®.

Interestingly, the control group (n=60) of this study revealed a high episiotomy rate (93.3%) in private term primiparous patients in our Singapore population. This reflects that most obstetricians in Singapore would prefer to perform an episiotomy rather than to allow a spontaneous laceration in the process of vaginal delivery of a term primiparous patient. It also confirms the impression that in Singapore, episiotomy is almost routine for the primiparous term patients in general. This high rate could be due to many possible factors, including relative Singapore mother-baby size differences, differences in the perineal tissue stretch ability and preparation for childbirth, differences in intrapartum practices, local women's preferences and attitude towards perineal preparation and episiotomy as well as attitudes, training and practices of local obstetricians in episiotomy and perineal trauma.

Some of the obvious factors here which would account for the higher episiotomy rates as in other studies[12-15] include primiparity, private patient status, delivery by obstetricians, use of epidural anaesthesia, and Indian and Chinese ethnicity. In a UK study[13] which surveyed factors for episiotomy and perineal tears in low-risk primigravidae, women from the Indian sub-continent were almost twice as likely and those from the Orient almost five times as likely to have an episiotomy, compared with white women; while US study[14] showed that black women were less likely to receive episiotomy than white women. Ethnicity is an important consideration in any studies involving episiotomy related outcomes.

It is also important to measure the overall perineal trauma rate. In our study, although the episiotomy rate was significantly reduced in cases using EPI-NO®, as in the Hillebrenner study, the overall perineal trauma rate was only slightly lower as a result of the higher spontaneous laceration rate in the EPI-NO® group. Thus, the beneficial aspect of a lower episiotomy rate in our study appeared to be negated by the increase in the spontaneous laceration rate in our population. This aspect was in contrast to the study by Hillebrenner et al which showed a lower perineal spontaneous laceration[11]. The postulated factors that may account for the increase in spontaneous laceration rate in this study include racial differences in elasticity and tissue properties of perineum and vagina, subtle technique and usage frequency differences, differences in delivery techniques and support, cephalo-pelvic relative size differences, as well as statistical random errors.

In our study, the degree of perineal tissue injury appeared to be less in the EPI-NO® group, especially

those with lacerations. In the EPI-NO® group, the mean length of spontaneous lacerations was shorter compared those of episiotomy cases, and three out of the 10 spontaneous laceration cases were only first degree tears. There was no third degree tear or significant multiple tears in the EPI-NO® group. Although the results suggested that EPI-NO® group had a lower rate of episiotomy, the overall perineal outcome was not significantly better in EPI-NO® group in our Asian population. Further studies, including randomised controlled trials, are needed. It is pertinent to continue to explore modalities that can reduce perineal trauma, and yet maintain good perinatal outcome and maternal satisfaction.

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