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July 2016, Volume 16, Number 2

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Editorial
From the Editor-in-Chief

I am most delighted to introduce this printed issue of the journal as the second issue of 2016. This is the second consecutive year that we are publishing two issues within the same year.

Once again we have a collection of interesting original articles contributed mainly by young investigators in our specialty. These include an innovative study on the use of intrapartum ultrasound to predict fetal spine and head position during the first and second stage of labour[1], a comparison of the use of transcutaneous bilirubin and serum bilirubin measurements in monitoring for neonatal jaundice in healthy Chinese newborns[2], a study of the risk factors for blood transfusion in Caesarean section so as to evaluate whether type and screen is mandatory for all such deliveries[3], as well as an analysis of the risk factors associated with vault haematoma following hysterectomy[4]. From the midwifery perspective, a very timely investigation of the factors that affect a mother's postnatal decision about infant feeding and the sustainability of breastfeeding ties in with the special theme of breastfeeding in this issue[5]. In addition, a case report on the novel use of preimplantation genetic diagnosis for a monogenic disease and aneuploidy screening with array comparative genomic hybridisation in Hong Kong highlights the newest technological advances in this area[6].

As well as original articles, we have also included a number of review articles to cover key contemporary developments in our specialty. The concept of using non-invasive prenatal testing as primary screening for Down syndrome is explored[7], and the controversial issues in the management of endometrial hyperplasia in the light of recently published authoritative guidelines locally and internationally are discussed[8]. In addition, perhaps as a special theme in this issue, to highlight the unanimous consensus across our specialty to support and promote breastfeeding and to strive towards baby-friendly hospital practices, there are two excellent reviews that illustrate the perspectives of obstetricians[9] and midwives[10]. Finally, an examination of the current legislation in Hong Kong on milk formula advertising for infants and young children attempts to put into context the obstacles we encounter in current breastfeeding promotion campaigns[11].

I hope you will all continue to enjoy and cherish the journal as a platform for sharing new scientific developments and enabling the exchange of viewpoints and opinions in our specialty.

William Wing-Kee TO MBBS, MPhil, MD, DipMed, FRCOG, FHKAM (O&G)
Editor-in-Chief, *Hong Kong Journal of Gynaecology, Obstetrics and Midwifery*

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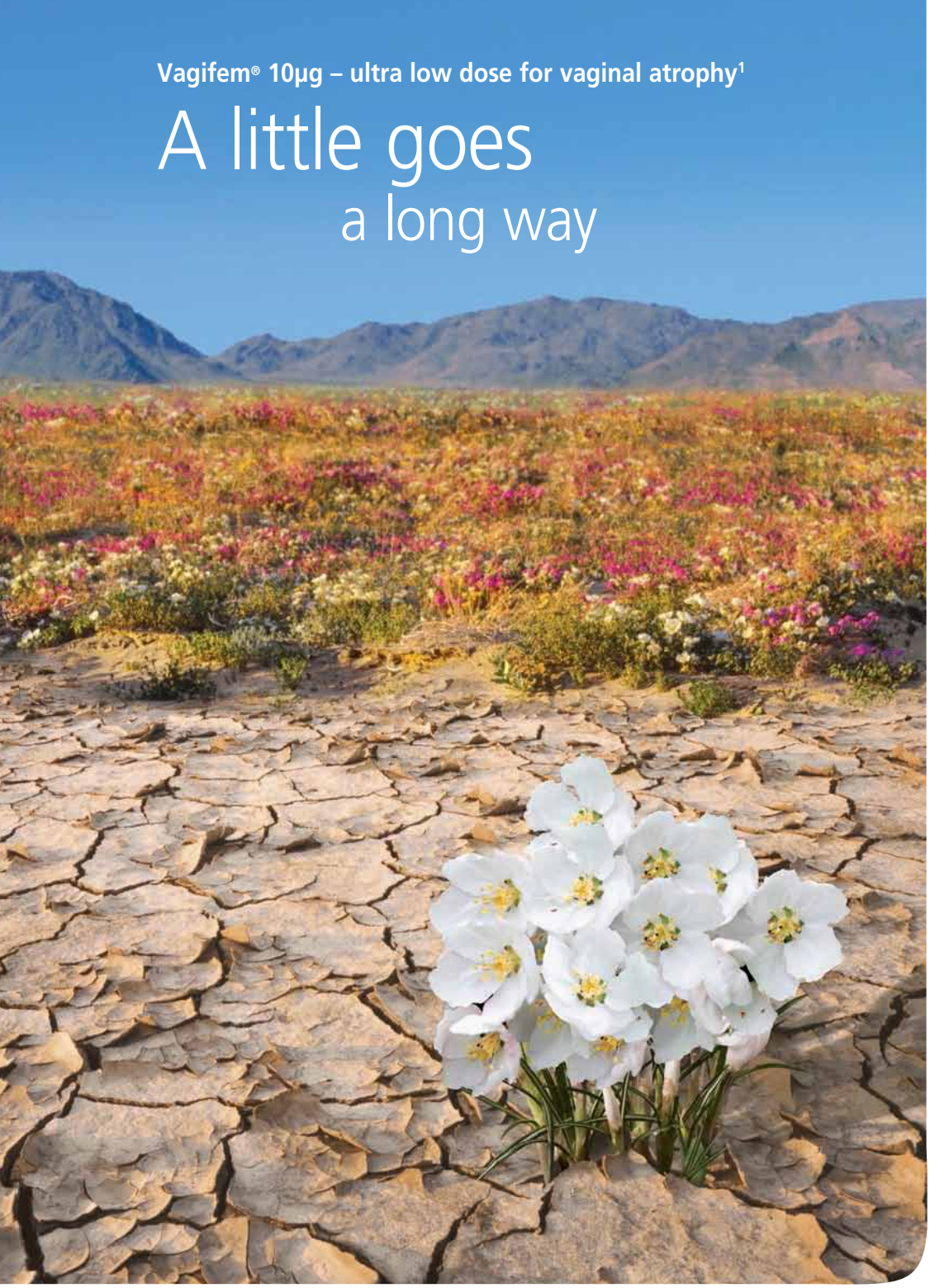

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Can Intrapartum Ultrasound Assessment of Fetal Spine and Head Position Predict Persistent Occiput Posterior Position at Delivery?

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Objective: To investigate the predictive value of fetal spine and head position in the first and second stages of labour measured by intrapartum ultrasound for persistent occiput posterior position at delivery in Chinese women in Hong Kong.
Methods: This was a prospective cohort study. A total of 100 women with a singleton term pregnancy in cephalic presentation underwent transabdominal ultrasound during the first or second stage of labour to measure fetal spine and head position. Fetal head position at birth was also recorded.
Results: Ninety-four women were included, of whom 35 and 51 were assessed in the first or second stage of labour, respectively, and eight were assessed at both stages. At the first stage, nine out of 43 fetuses were in the occiput posterior position with eight having a posterior spine position; one baby was delivered in the occiput posterior position. At the second stage, nine out of 59 fetuses were in occiput posterior position, with seven having a posterior spine position. Two (28.5%) fetuses with both spine and occiput at posterior position were delivered in that position. As the majority of fetuses with occiput posterior position in the first stage were delivered in a non–occiput posterior position, data obtained at the second stage were used for analysis. The positive predictive value of fetal spine and head position was 25% and 22.2%, respectively, whereas negative predictive value of both positions was 98%.
Conclusions: Fetal spine and head position assessed using ultrasound during the second stage of labour may be helpful in cases of persistent occiput posterior position at delivery and thus allow manoeuvres to be performed to facilitate delivery.
Hong Kong J Gynaecol Obstet Midwifery 2016; 16(2):102-7

Keywords: Head/embryology; Labour presentation; Spine/embryology; Ultrasonography, prenatal

Introduction

Occiput posterior (OP) position is considered to be a common fetal malposition during labour[1]. It happens in about 15% to 20% of pregnancies in the first stage of labour[2-4]. At delivery, 5% of fetuses remain in the OP position, mainly due to failure of internal rotation or malrotation during descent[2-4].

Delivery in the OP position is associated with increased maternal and neonatal morbidiy[1]. Apart from a higher risk of prolonged labour and chorioamnionitis, the need for oxytocin augmentation, instrumental delivery or Caesarean section is also increased[5]. Third- or fourth-degree perineal tears, and excessive blood loss are also associated with OP deliveries[1]. Poorer Apgar scores, lower umbilical artery pH, higher risk of meconium-stained fluid and meconium aspiration syndrome, birth trauma, and need for neonatal intensive care support are more common among infants born in the OP position[6].

Intrapartum ultrasound may improve the accuracy of detecting fetal head position[7]. Blasi et al[8] demonstrated the accuracy of detecting fetal spine and head position by ultrasound during the second stage of labour. Both fetal spine and head position had a sensitivity of 100%, while specificity of fetal spine position was 99% and specificity of fetal head position being 78%[8]. Gizzo et al[9] investigated the role of fetal spine position detection during labour in predicting OP delivery and associated obstetric complications. Fetal spine position had a sensitivity of 93.7% and specificity of 100% when predicting OP

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delivery[9]. Data of fetal head position were also included and had a sensitivity of 87.5% and a specificity of 86.5%[9].

This study aimed to determine the usefulness of intrapartum ultrasound assessment of fetal spine and head position to predict persistent OP position at delivery in Chinese women in Hong Kong. To the best of our knowledge, no similar local study has been performed in Hong Kong.

Methods

This was a prospective cohort study performed in the labour ward at Kwong Wah Hospital, Hong Kong from May 2011 to June 2012. A portable two-dimensional (2D) ultrasound machine (MyLab 25; Esaote, Florence, Italy) with transabdominal 2D probe was readily available in the labour ward and was used for intrapartum ultrasound in all women.

Women were enrolled when they were in the first or second stage of labour. Term (37-42 weeks of gestation), singleton pregnancies with cephalic presentation were included. Women who were already scheduled for Caesarean section before labour onset, or those with suspected fetal distress were excluded. All participants were informed of the principle and the procedure of the study. Verbal consent for examination was obtained from all of them before ultrasound, after approval by our hospital's ethics committee.

Maternal features and labour characteristics including maternal age, parity, spontaneous or induced labour, mode of delivery, and birth weight were recorded.

Stages of labour were established by labour ward staff. Onset of labour was defined as regular painful uterine contractions with cervical dilatation of ≥3 cm, and second stage of labour started at the time of full cervical dilatation.

The ultrasound examinations were performed by three researchers (two specialist trainees with 4-6 years of experience, and one specialist obstetrician with more than 6 years of experience). A workshop was conducted for all operators with supervision by the most senior operator (the fourth author). Women were in a supine position and the ultrasound transducer was placed longitudinally on the abdomen first to identify the cervical spine and occipital bone of the fetus, then transversely to obtain position of the fetal spine column, fetal cerebral echo, and fetal cerebellum. Other landmarks were also used to determine the fetal head position (fetal orbits for OP position, midline cerebral echo for occiput transverse [OT] position, and midpoint of cerebellum for occiput anterior [OA] position). The position of the fetal spine and occipital bone was recorded on a clock-like chart divided into 24 sections (Figure 1), each of 15 degrees (anterior: 9.30-2.29, left transverse: 2.30-3.29, posterior: 3.30-8.29, right transverse: 8.30-9.29). All images were checked and the findings verified offline by the most senior operator. Fetal head position at birth was also recorded by attending midwives or doctors with the same algorithm. All parties were blinded to each other's findings.

In our analysis, all spine and occiput positions were classified as posterior or non-posterior, the latter including anterior and bilateral transverse positions.

Statistical Analysis

The data were entered into an Excel file (Microsoft, US) by one of the researchers. The data were then analysed by Excel (Microsoft, US). Maternal features, labour characteristics and outcome were summarised using percentages, means, and medians. The sensitivity, specificity, predictive values, and likelihood ratios of intrapartum assessment of fetal spine and head position in predicting persistent OP position at delivery were calculated in 2 x 2 tables. 95% Confidence intervals were calculated by Wilson method and binomial exact (Clopper-Pearson) test. Likelihood test was also done in 2 x 2 tables.

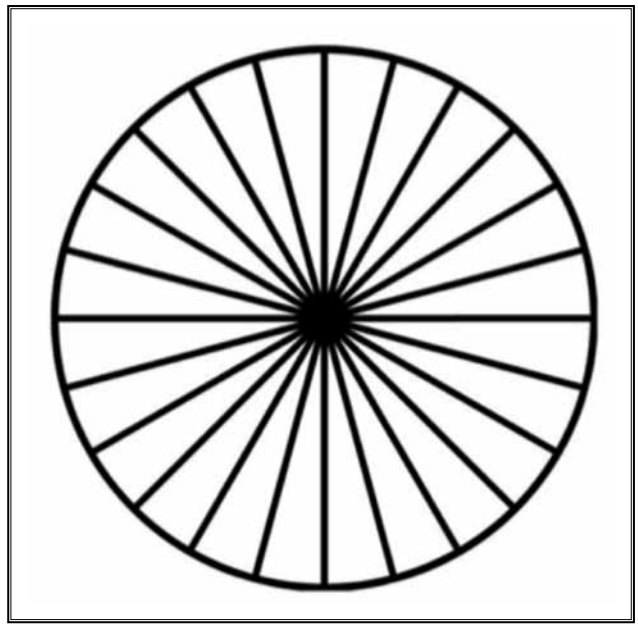

Figure 1. Clock-like chart with 24 divisions (each 15 degrees) used for fetal head and spine position determination

Results

A total of 100 eligible women were recruited. Six women were excluded as they underwent emergency lower segment Caesarean section during the first stage of labour. Ninety-four women were included for analysis: 35 of them were assessed during the first stage of labour, 51 were assessed in second stage, and eight were assessed during both first and second stages (Figure 2).

The maternal features and labour characteristics are summarised in Table 1. The median maternal age was 32 years and the median gestational age at assessment was 40 weeks. The median birth weight was 3.35 kg.

Among the fetuses of 43 women assessed during the first stage of labour, 29 (67.4%) fetuses were in OA position, whereas five (11.6%) in OT position and nine (20.9%) in OP position. Among these nine fetuses in OP position, eight were also in posterior spine position but only one (12.5%) delivered in OP position (Table 2).

When using fetal head position to predict persistent OP position at delivery, sensitivity was 100% and specificity was 80.95%. The positive predictive value (PPV) was 11.11% and negative predictive value (NPV) was 100%. Positive likelihood ratio (LR+) was 5.25 and negative likelihood ratio (LR-) was 0. When predicting persistent OP position at delivery by fetal spine position, sensitivity was 100% and specificity was 83.33%. The PPV was 12.5% and NPV was 100%; LR+ was 6 and LR- was 0.

For the fetuses of 59 women assessed during the second stage of labour, 46 (78.0%) fetuses were in OA position, whereas four (6.8%) in OT position and nine (15.3%) in OP position. Seven of these nine fetuses in OP position were also found to have posterior spine position. Two (28.6%) of these seven fetuses remained in OP position at delivery. One fetus presented with OA position

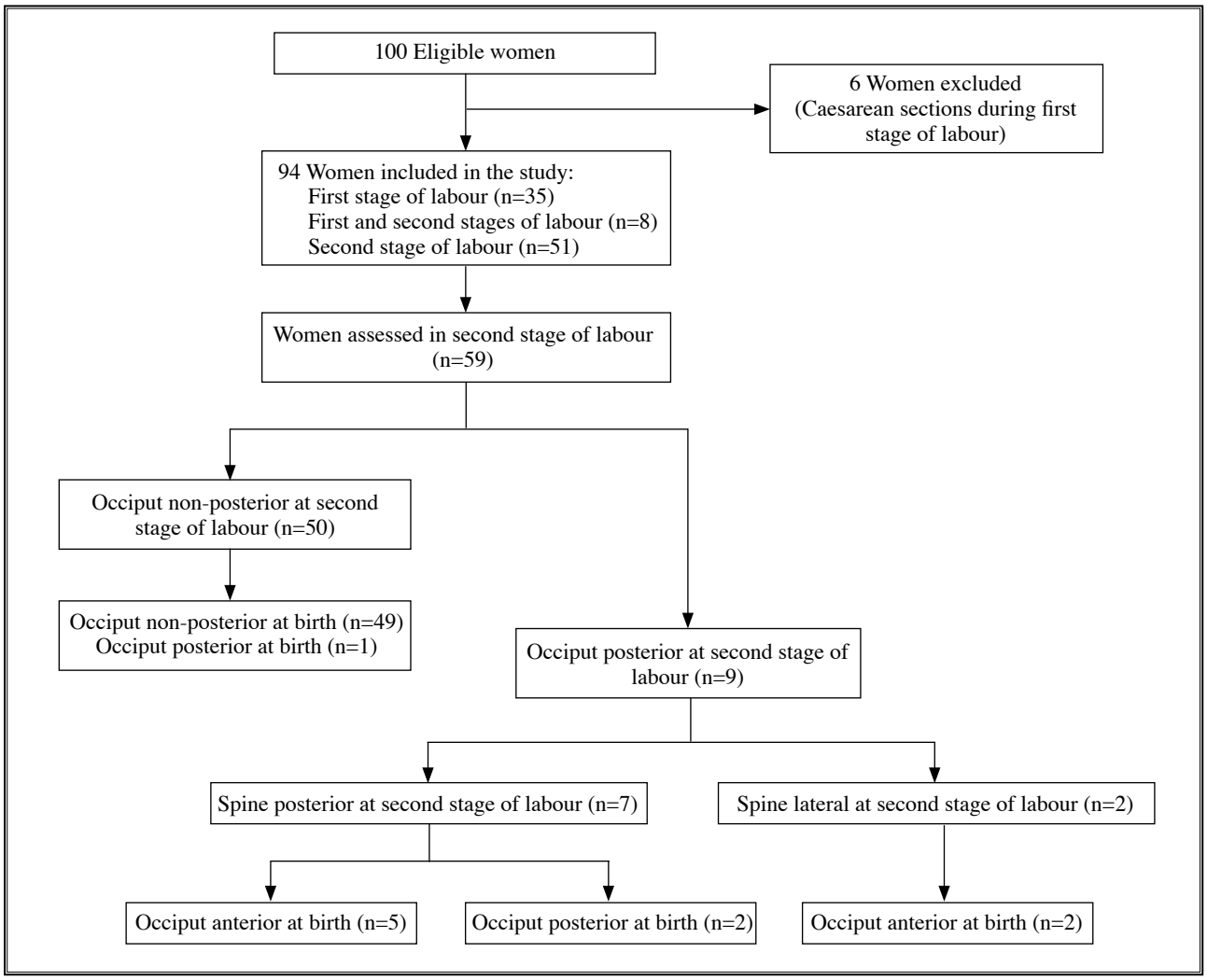

Figure 2. Flowchart showing occiput and spine positions of the patients in the study

Table 1. Maternal features and labour characteristics of the study subjects (n=94)

	No. (%) of women
Maternal age (years)	
<20	1 (1.1)
20-34	82 (87.2)
≥35	11 (11.7)
Parity	
Nulliparous	80 (85.1)
Parious	14 (14.9)
Labour	
Spontaneous	25 (26.6)
Induction	45 (47.9)
Augmentation	24 (25.5)
Mode of delivery	
Spontaneous	74 (78.7)
Vacuum	15 (16.0)
Forceps	1 (1.1)
Caesarean section	4 (4.3)
Birth weight (kg)	
<3	16 (17.0)
3-3.99	74 (78.7)
≥4	4 (4.3)

Table 2. Occiput and spine positions in the first and second stages of labour and at delivery*

Stage of labour	Position		
	Transverse	Anterior	Posterior
First stage (n=43)			
Occiput	5 (11.6)	29 (67.4)	9 (20.9)
Spine	8 (18.6)	27 (62.8)	8 (18.6)
Second stage (n=59)			
Occiput	4 (6.8)	46 (78.0)	9 (15.3)
Spine	9 (15.3)	42 (71.2)	8 (13.6)
At birth (n=94)			
Occiput	3 (3.2)	87 (92.6)	4 (4.3)

* Data are shown as No. (%) of subjects

and transverse spine position in the second stage of labour but delivered in OP position. A total of four infants were born in OP position in our study group (Table 2).

Two of the three fetuses that delivered in OP position were noted to have OP position during ultrasound in the second stage of labour, resulting in a sensitivity of 66.7% for predicting OP position at birth. For 56 infants born in non-OP position, 49 were diagnosed with non-OP position on ultrasound during the second stage of labour, resulting in a specificity of 87.5%. The PPV was 22.2% and NPV was 98%. The LR+ was 5.34 while LR- was 0.38 (Tables 3 and 4).

Similar findings were noted for predicting OP position at delivery by detecting fetal spine position on ultrasound during the second stage of labour. Sensitivity of 66.7% and specificity of 89.3% were found. The PPV was 25% and NPV was 98%, whereas LR+ was 6.23 and LR- being 0.37 (Tables 3 and 4).

Discussion

In this study, the incidence of OP position in the first stage of labour (20.9%) and OP position at delivery (4.3%) was comparable with other studies[2-4].

Although most of our women assessed during the first and second stage of labour belonged to separate groups, we could deduce that the majority of fetuses with OP position during the first stage would change to non-OP position at second stage, and is compatible with previous studies[2-4,10]. After our analysis of data in both stages, we focused the prediction of persistent OP position at birth on the data of second stage only as it was more reliable.

Our results echoed those from previous studies[8,9]. When the fetal head was in OP position at the second stage, only two out of the seven fetuses with co-existing posterior

Table 3. Intrapartum ultrasound evaluation of occiput and spine positions in the second stage of labour in relation to occiput posterior position at delivery*

Ultrasound finding	Occiput position at birth		
	Posterior (n=3)	Non-posterior (n=56)	Total (n=59)
Occiput			
Posterior	2 (3.4)	7 (11.9)	9 (15.3)
Non-posterior	1 (1.7)	49 (83.1)	50 (84.7)
Spine			
Posterior	2 (3.4)	6 (10.2)	8 (13.6)
Non-posterior	1 (1.7)	50 (84.7)	51 (86.4)

* Data are shown as No. (%) of subjects

Table 4. Sensitivity, specificity, PPV, NPV, LR+, LR-, and their 95% CIs for occiput and spine positions in the second stage of labour in predicting occiput posterior position at birth

Characteristic	Occiput position		Spine position	
	Value	95% CI	Value	95% CI
Sensitivity	0.667 (2/3)	0.094-0.992*	0.667 (2/3)	0.094-0.992*
Specificity	0.875 (49/56)	0.764-0.938	0.893 (50/56)	0.785-0.950
PPV	0.222 (2/9)	0.028-0.600*	0.25 (2/8)	0.032-0.651*
NPV	0.98 (49/50)	0.895-0.997	0.98 (50/51)	0.897-0.997
LR+	5.34	1.851-15.371†	6.23	2.069-18.709†
LR-	0.38	0.077-1.893†	0.37	0.075-1.854†

Abbreviations: 95% CI = 95% confidence interval; LR+ = positive likelihood ratio; LR- = negative likelihood ratio; NPV = negative predictive value; PPV = positive predictive value

* Calculated by binomial exact (Clopper-Pearson) test. Others are by Wilson method

† Likelihood test by 2 x 2 table

spine position were delivered in OP position. On the contrary, there was no case of delivery in OP position when the fetal spine was in non-posterior position. Nonetheless, it was uncommon for the fetus to be delivered in OP position when fetal head was in non-OP position.

Both fetal spine and head position had similar sensitivity and specificity. High specificity and NPV could help estimate the probability of persistent OP position at delivery. If fetal spine position is non-posterior, there is a higher chance of delivery in non-OP position.

To the best of our knowledge, this is the first such study of Chinese women in Hong Kong. When compared with the study by Blasi et al[8], our prevalence of OP position was lower and similar to the findings in other studies[2-4]. This might be related to lower epidural analgesia administration in our unit (about 1% from our departmental statistics within the study period)[11] than their study group (32%)[8]. Indeed, there were only two women with epidural analgesia in our group. Epidural analgesia is infrequent in our unit because many women choose other pain relief, e.g. massage, music therapy, birth ball, and opioid analgesics[12]. Also, epidural analgesia may not be always available round the clock due to lack of anaesthetist support, especially outside of office hours[12]. There is already evidence from earlier studies of a higher risk of persistent OP position at delivery when women receive epidural analgesia[10].

The limitations of our study included small sample size of persistent OP position at delivery. Further studies with larger sample size are required for better confirmation of our results. Our study mainly focused on the accuracy of intrapartum ultrasound to predict occiput position at delivery. Other aspects including associated clinical implications of persistent OP position, such as prolonged labour, need for operative vaginal delivery or Caesarean section, or adverse neonatal outcome should be explored in the future.

Prediction of persistent OP position at delivery is important for intrapartum management as it carries risk to both mother and infant[5,6]. Unfortunately, sometimes it is difficult to detect fetal head position accurately during active labour and correct identification by digital vaginal examination happens only in two thirds of women in general[13]. Intrapartum ultrasound can improve the accuracy of identifying those women who may anticipate difficulty in vaginal delivery and may need operative delivery. It may also provide more clinical information when considering manual rotation of the fetal head before delivery[9]. Intrapartum ultrasound is safe and easily accessible in most labour wards in developed areas around the world. The results of our study support the application of intrapartum ultrasound to predict persistent OP position at delivery to reduce maternal and neonatal morbidity and facilitate intrapartum management.

Declaration

All authors have disclosed no conflicts of interest.

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Discrepancy between Transcutaneous and Serum Bilirubin Measurement in Healthy Chinese Newborns in a Baby-friendly Hospital in Hong Kong

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Objective: To characterise the discrepancy between transcutaneous bilirubin (TcB) and total serum bilirubin (TSB) levels and to evaluate the use of TcB measurements in detection of severe hyperbilirubinaemia requiring phototherapy among healthy Chinese newborns.
Methods: Medical records were reviewed to collect data on paired TcB-TSB measurements. The paired TSB level was obtained within 2 hours of the TcB measurement in healthy Chinese neonates admitted to one of our postnatal wards over a 1-year period, from January to December 2015. Demographic information and outcome for individual newborns were also recorded. TcB-TSB differences were calculated and analysed in order to obtain their correlations. Multivariate regression analysis was used to identify characteristics independently associated with TcB-TSB difference of ≥20 and ≥30 μmol/L. The clinical application of TcB, together with Bhutani nomogram in the prediction of severe hyperbilirubinaemia in medium- and higher-risk thresholds for phototherapy was also analysed.
Results: A total of 220 TSB levels were matched with a TcB value. The correlation between paired measurements was 0.75. The mean TcB-TSB difference was 28.76±23.83 μmol/L. TcB measurements in general tended to overestimate TSB, although the TcB-TSB difference varied with different TSB values and TcB measurements tended to be underestimated as TSB levels increased. Using the 75th centile tract of Bhutani nomogram as threshold, TcB measurements could predict all cases in the high-risk zone with a sensitivity and negative predictive value of 100% each. At medium-risk and higher-risk thresholds for phototherapy, using the 75th centile as the cut-off level, the sensitivity was 93.2% and 73.1%, respectively.
Conclusions: TcB measurement provided a reasonable estimate of TSB in healthy newborns with a high breastfeeding rate. As TcB-TSB difference varied with different TSB levels, caution should be taken especially in cases with severe hyperbilirubinaemia in which TcB measurements tended to be underestimated with higher TSB level. Combining the use of TcB measurements and the 75th centile tract of Bhutani nomogram as the cut-off level can detect all high-risk cases of severe hyperbilirubinaemia.
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Keywords: Bilirubin/blood; Hyperbilirubinemia; Jaundice, neonatal; Neonatal screening

Introduction

Neonatal jaundice (NNJ) is one of the most common diseases encountered during the early neonatal period and is more prevalent in the Asian population compared with Caucasians. A study in Hong Kong showed that 87% of full-term Chinese newborns had clinical jaundice, of whom 23.9% had a peak total serum bilirubin (TSB) of >204 μmol/L[1]. Severe unconjugated hyperbilirubinaemia can lead to irreversible brain damage, namely kernicterus. Prevention of kernicterus in neonates is a primary focus of neonatal care in the postnatal nursery unit. Visual estimates of the degree of jaundice and the serum bilirubin level can be misleading[2-4]. To promote early detection of significant hyperbilirubinaemia, the Subcommittee on Hyperbilirubinemia of the American Academy of Pediatrics recommended that all newborns be screened before discharge with transcutaneous bilirubin (TcB) or TSB measurement[5]. TcB measurement is a quick and non-invasive alternative to invasive blood taking to screen for NNJ. Studies have shown that TcB is highly correlated with TSB, with a correlation coefficient of around 0.8 in both international and local studies[6-8]. Differences between TcB and TSB (TcB-TSB difference) are associated with different ethnic origin, age (in hours) of when TcB measurement was taken, and different TSB levels[6].

Our hospital is one of the major public hospitals in Hong Kong that serves a mostly Chinese population. There is evidence of a good correlation between TcB and

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TSB in Chinese infants[7,8]. A study in the US showed that the TcB-TSB difference becomes larger with each hour of advancing age, even after adjusting for TSB level[6]. Local studies suggested that the mean TcB-TSB difference was 21.7 μmol/L when TcB measurements were taken in the first 3 days of life[7], compared with 14 μmol/L when taken at 3 to 7 days of life[8]. Whether there is any association between the TcB-TSB difference and the hours of age in Chinese infants remains unknown.

Both Chinese ethnicity and breastfeeding are associated with a higher maximum TSB level in newborns[9]. With the promotion of breastfeeding and recent baby-friendly hospital initiative in our hospital, the rate of exclusive breastfeeding in our department has almost doubled from 22.8% in 2013 to 41.2% in 2015 (personal communication from our breastfeeding consultant). One may expect to see more newborns with a higher TSB level in our department. Since September 2014, our hospital had started to use a higher cut-off TSB threshold for phototherapy, modified from the American Academy of Pediatrics (AAP) guideline published in 2004[10]. According to this guideline, East Asian race is one of the major risk factors for babies to develop severe hyperbilirubinaemia. Therefore, in our hospital, we adopted the higher-risk threshold in infants who were 35-0/7 to 37-6/7 weeks at birth and well or ≥38 weeks with risks. In those who were ≥38 weeks and well, we adopted the medium-risk threshold instead of the medium-risk and lower-risk thresholds, respectively for phototherapy according to the AAP. This change was supported by a subsequent consensus guideline issued by the Hospital Authority hospitals[11]. If a TcB level is within the threshold for phototherapy (20-35 μmol/L) then TSB measurement is recommended. Although TcB measurements are an overestimation and cause unnecessary blood taking, they provide a safety margin for confirmation and further monitoring. On the contrary, TcB underestimation can be potentially dangerous when infants do not have TSB level checked and can lead to potential missed diagnosis and delayed treatment of severe hyperbilirubinaemia. A study in the US in which the majority of subjects were white showed that at higher serum bilirubin levels, TcB tended to underestimate the TSB level with substantial variability when TSB level was ≥256.5 μmol/L[6]. Studies have suggested that the use of TcB measurements together with the Bhutani nomogram could improve the identification of cases with significant hyperbilirubinaemia[7,12,13].

The present study aimed to characterise the discrepancies between TcB measurements and TSB levels at different TSB levels and with different newborn variables among term or near-term healthy Chinese newborns. The clinical application of TcB measurements, together with the Bhutani nomogram in the prediction of severe hyperbilirubinaemia in medium-risk and higher-risk thresholds for phototherapy, were also analysed in order to facilitate NNJ screening and avoid unnecessary blood tests.

Methods

A retrospective study was carried out on healthy term neonates admitted to a postnatal ward in a regional hospital in Hong Kong. According to our departmental protocol, all newborns discharged from our postnatal ward are screened by TcB measurement before discharge using JM-103 Minolta (Dräger Medical Systems Inc., Telford [PA], US). Two readings were measured from the sternum by a nurse and the higher reading was recorded. If a TcB level is within the threshold for phototherapy of 20 to 35 μmol/L, a TSB measurement by a direct spectrophotometric method in the laboratory will be done. Medical records were reviewed on all healthy Chinese newborns admitted to the postnatal nursery between January and December 2015. Healthy neonates with no evidence of birth trauma, neonatal infection, asphyxia, Chinese descendants, near-term and term infants of ≥35 weeks of gestation, and no evidence of rhesus isoimmunisation were included. Non-Chinese infants, preterm infants of <35 weeks of gestation, sick newborns who required admission to the special care baby unit (SCBU) or neonatal intensive care units (NICU), and newborns who had received phototherapy were excluded. For each eligible newborn, demographic data and outcome were retrieved from the medical records, including gestational age, sex, birth weight, type of feeding (exclusive breast milk, mixed breast milk and formula, only formula), glucose-6-phosphate dehydrogenase (G6PD) status, type of delivery, maternal blood group, readmission for NNJ, and whether phototherapy or exchange transfusion were given. The results of all TcB tests for each enrolled newborn were abstracted along with the infant's age (in hours) and time when the measurement was made. In addition, data on TSB measurement performed within 2 hours of a TcB measurement were obtained. TcB and TSB measurements that were obtained within 2 hours of each other were considered paired.

Outcome and Statistical Analyses

The Statistical Package for the Social Sciences (SPSS V.21; IBM, US) was used for statistical analysis. The primary study outcome was the TcB-TSB difference between paired values, such that a positive difference indicated that the TcB value was greater than the

corresponding TSB level and a negative difference indicated that the TcB measurement was less. Only the first paired TcB-TSB values of each eligible infant were used in the analyses. In addition to descriptive statistics, the correlation between paired TcB and TSB level was determined by Pearson product-moment correlation coefficient. The association of different patient characteristics with the TcB-TSB difference, including gestational age at birth, birth weight, gender, type of feeding, G6PD status, maternal blood group, type of delivery, hours of age when TcB was measured, TSB level and neonatal outcome, were individually assessed using regression analyses. Because the magnitude of the TcB-TSB difference might vary based on the TSB level, TSB levels were included in all regression models. Patient variables statistically associated with a TcB-TSB difference ($p<0.05$) in bivariate analyses were included in a full model to identify characteristics independently associated with the difference.

Proportions of clinically relevant underestimations and overestimations for ≥20 and ≥30 μmol/L between paired TcB-TSB samples were determined. Logistic regression was used to identify characteristics associated with clinically relevant underestimations of TSB by TcB (i.e. TcB levels ≥20 μmol/L or ≥30 μmol/L lower than the corresponding TSB value). Those variables statistically associated with the outcome in bivariate analyses were included in a multivariate model. For all analyses, TSB levels were included. A similar analytic strategy was used to identify characteristics associated with clinically relevant overestimations of TSB by TcB measurement.

The ability of various TcB cut-off values to predict elevated TSB value was analysed using standard 2 x 2 table analysis. Sensitivity, specificity, as well as positive and negative predictive values were calculated. The Bhutani nomogram[12] was used to identify risk zones for bilirubin values. The percentage of blood taking avoided was calculated ([false negatives + true negatives] / total No. of comparisons). The clinical value of TcB level for prediction of severe hyperbilirubinaemia above the medium-risk and higher-risk thresholds for phototherapy according to the AAP guidelines[10] was also determined. The sensitivity and specificity of TcB level in different hour-specific risk zones of Bhutani nomogram (40th, 75th and 95th centiles) for medium- and higher-risk thresholds for phototherapy was then calculated.

The study was approved by the Hospital Authority Research Ethics Committee (Kowloon Central/ Kowloon East).

Results

A total of 1266 newborns were admitted to the postnatal ward during the 1-year study period. Newborns with at least one blood sample taken for TSB measurement were identified through the Clinical Data Analysis and Reporting System and 559 records were reviewed. After excluding non-Chinese newborns, newborns who became sick and required transfer to SCBU/NICU, and non-paired TcB-TSB samples (i.e. TSB taken >2 hours apart from TcB measurement), a total of 220 healthy term Chinese newborns contributed to the study. Their characteristics and outcome are summarised in Table 1. All were term infants of ≥37 weeks of gestation. All women with Rhesus D–positive status showed no risk of rhesus isoimmunisation. The majority (95.0%) of neonates were either exclusively or partially breastfed.

The TSB value in study newborns ranged from 76 μmol/L to 293 μmol/L; 12 (5.45%) of whom being ≥250 μmol/L. Overall, the mean (±standard deviation) TcB-TSB difference for the 220 paired measurements was 28.76±23.83 μmol/L, with differences ranging from -30 μmol/L to 94 μmol/L, following a normal distribution verified by Shapiro-Wilk test ($p=0.53$). The majority (94.5%) of the paired TcB-TSB samples were obtained on days 2 and 3. The correlation coefficient between paired measurements was significant ($r=0.75$; $p<0.001$).

The TcB-TSB difference varied with the TSB level (Figure 1). The mean TcB-TSB difference for the five paired measurements, when TSB level was ≤125 μmol/L, was 35.4 μmol/L (95% confidence interval [CI], 0.18-70.62 μmol/L). The mean TcB-TSB difference became progressively less positive as the TSB level increased, with a mean TcB-TSB difference of 18.8 μmol/L (95% CI, 2.9-34.7 μmol/L) for the 10 paired measurements when TSB level was ≥251 μmol/L. The regression coefficient was -0.382 (95% CI, –0.353 to –0.180; $p<0.001$). A Bland-Altman plot of all 220 comparisons showed that TcB measurement overestimated TSB level in the majority of comparisons, and the bias was +28.8 μmol/L (Figure 2). After controlling for TSB level, no neonatal characteristic was significantly associated with TcB-TSB difference (Table 2).

There were seven (3.2%) neonates with a TcB level ≥20 μmol/L lower than the corresponding TSB level, and 150 (68.2%) neonates with a TcB level ≥20 μmol/L higher than the corresponding TSB level. Overall, TcB reading differed from the matched TSB value by a ≥20 μmol/L difference in 71% (95% CI, 65-77%) of cases. The analysis of the association of individual newborn characteristics

Table 1. Characteristics of newborns and their outcome with at least one paired TcB-TSB level (n=220)*

Characteristics	Data
Gestational age (weeks)	39.1 ± 1.0
Birth weight (g)	3208 ± 323
Gender	
Male	120 (54.5)
Female	100 (45.5)
Mean (range) hours of age	52.6 (8.0-124.6)
Vaginal delivery	150 (68.2)
Feeding	
Exclusive breast	150 (68.2)
Breast and formula	59 (26.8)
Formula only	11 (5.0)
G6PD deficiency	12 (5.5)
Maternal blood group	
A	50 (22.7)
B	47 (21.4)
AB	14 (6.4)
O	109 (49.5)
Excessive weight loss >7% on day 2/3	138 (62.7)
Excessive weight loss >10% on day 2/3	20 (9.1)
Outcomes	
Readmission for NNJ†	106 (48.2)
Phototherapy given‡	85 (38.6)
Exchange transfusion given‡	1 (0.5)

Abbreviations: G6PD = glucose-6-phosphate dehydrogenase; NNJ = neonatal jaundice; SCBU = special care baby unit; TcB-TSB level = transcutaneous bilirubin–total serum bilirubin level

* Data are shown as mean ± standard deviation or No. (%) of subjects, unless otherwise specified

† Readmission for NNJ was defined as newborns who were already discharged home from postnatal ward and were readmitted to SCBU for NNJ

‡ Phototherapy / exchange transfusion received either before discharge or during readmission for NNJ

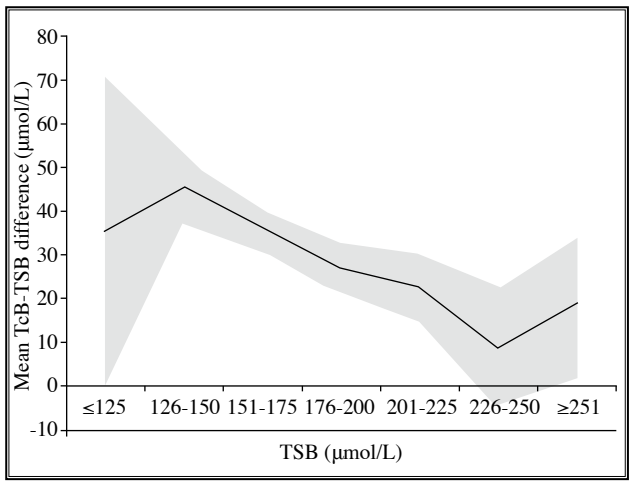

Figure 1. Mean TcB-TSB difference at different ranges of TSB levels

The shaded area represents the 95% confidence intervals around the means

Abbreviations: TcB = transcutaneous bilirubin; TSB = total serum bilirubin

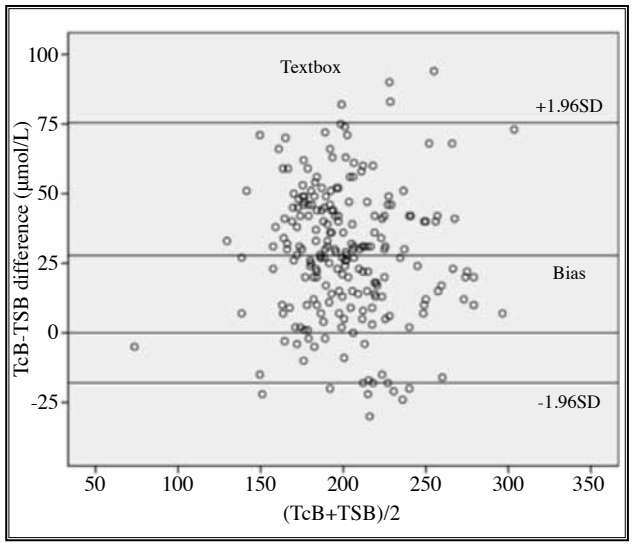

Figure 2. Bland-Altman plot comparing TSB and TcB

Abbreviations: SD = standard deviation; TcB = transcutaneous bilirubin; TSB = total serum bilirubin

with a TcB level ≥20 or ≤20 μmol/L than the corresponding TSB level is summarised in Table 2. The TSB level was significantly associated with an overestimation of TcB ≥20 μmol/L with the matched TSB level, with an odds ratio of 0.976 (95% CI, 0.966-0.985). Both TSB level and hours of age when TcB measurement was taken were significantly associated with an underestimation of TcB ≥20 μmol/L with the matched TSB level, with an odds ratio of 1.029 (95% CI, 1.008-1.051) and 0.920 (95% CI, 0.856-0.988), respectively (Table 2).

One (0.45%) neonate had a TcB level ≥30 μmol/L lower than the corresponding TSB level, and 111 (50.4%) neonates with a TcB level ≥30 μmol/L higher than the corresponding TSB level. Overall, TcB reading differed from the matched TSB value by a ≥30 μmol/L difference in 50.9% (95% CI, 44-58%) of cases. The analysis of the association of individual newborn characteristics with a TcB

level ≥30 μmol/L higher than the corresponding TSB level is summarised in Table 2. Both gestational age and TSB level were significantly associated with overestimation of TcB ≥30 μmol/L with the matched TSB level, with an odds ratio of 1.363 (95% CI, 1.030-1.805) and 0.976 (95% CI, 0.966-0.985), respectively. Similar analysis could not be done for the single newborn with a TcB level 30 μmol/L lower than the corresponding TSB level because of the low frequency of the outcome (n=1, 0.45%).

Regarding the AAP risk zone distribution of TSB values, 27 (12%) were in low-risk zone, 105 (48%) in low-intermediate risk zone, 71 (32%) in high-intermediate risk zone, and 17 (8%) in high-risk zone. For those in the high-risk zone, the corresponding distribution of TcB measurements was two (12%) in the high-intermediate risk zone and 15 (88%) in high-risk zone. Results of data analysis using hour-specific risk zones are shown in Table 3. A TSB value in the high-risk zone could be predicted by a TcB measurement in or above the high-intermediate risk zone, with a sensitivity and negative predictive value of 100% each. The application of 75th centile tract could reduce 25% of blood tests. Among the 17 TSB values in the high-risk zone, 16 (94.1%) subsequently required phototherapy. If the medium-risk (≥38 weeks and well) threshold for severe hyperbilirubinaemia was used for prediction, the sensitivity of using the 40th, 75th, and 95th centile tracts was 100%, 93.2% and 40.7%, respectively. If the higher-risk (35-0/7 to 37-6/7 weeks and well or ≥38 weeks with risks) thresholds for severe hyperbilirubinaemia was used for prediction, the sensitivity of using the 40th, 75th, and 95th centile tracts was 100%, 73.1% and 26.9%, respectively. On the contrary, the specificity for the 95th centile tract was 100% (Table 4).

Table 2. Association between individual patient characteristics and TcB-TSB difference, and TcB values that were ≥20 or ≤20, or ≥30 μmol/L than the corresponding TSB level

Variable	Coefficient*	p Value*	Outcome (odds ratio [95% confidence interval])		
			TcB ≥20 μmol/L higher than TSB	TcB ≥20 μmol/L lower than TSB	TcB ≥30 μmol/L higher than TSB
Hours of age	-0.30	0.660	1.002 (0.976-1.028)	0.920 (0.856-0.988)	0.987 (0.964-1.01)
Gestational age	0.116	0.065	1.167 (0.863-1.579)	0.362 (0.122-1.074)	1.363 (1.030-1.805)
Birth weight	-0.02	0.754	1.000 (0.999-1.001)	0.998 (0.995-1.001)	1.000 (0.999-1.001)
Gender	-0.017	0.785	0.861 (0.467-1.587)	0.166 (0.019-1.488)	0.712 (0.402-1.263)
G6PD deficiency	-0.041	0.519	1.763 (0.473-6.499)	0.496 (0.050-4.928)	1.109 (0.293-4.205)
Feeding (exclusive breastfeeding)	-0.043	0.495	1.045 (0.542-2.014)	0.294 (0.034-2.580)	0.968 (0.523-1.79)
Excessive weight loss >7%	-0.063	0.328	1.339 (0.695-2.579)	1.027 (0.182-5.789)	1.528 (0.841-2.776)
TSB level	-	-	0.976 (0.966-0.985)	1.029 (1.008-1.051)	0.976 (0.966-0.985)
Mode of delivery	-0.004	0.946	-	-	-
Maternal blood group	0.004	0.952	-	-	-

Abbreviations: G6PD = glucose-6-phosphate dehydrogenase; TcB = transcutaneous bilirubin; TSB = total serum bilirubin
* Coefficients and p values determined with regression analysis after controlling for TSB level

Table 3. TSB levels and TcB cut-off values related to AAP risk zones[7]

TSB zone*	TcB zone*	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Blood tests avoided† (%)
4	4	0.88	0.78	0.25	0.99	72.7
4	≥3	1.0	0.28	0.10	1.0	25.5
≥3	≥3	0.93	0.38	0.50	0.89	25.5
≥3	≥2	1.0	0.008	0.40	1.0	0.5

Abbreviations: AAP = American Academy of Pediatrics; TcB = transcutaneous bilirubin; TSB = total serum bilirubin
* Classification of zones: zone 2 = low-intermediate risk; zone 3 = high-intermediate risk; zone 4 = high risk
† Calculated by: (false negatives + true negatives) / total No. of comparisons

Table 4. Statistical analysis for phototherapy with medium-risk and higher-risk thresholds

Transcutaneous bilirubin category	Phototherapy		Sensitivity (95% confidence interval)	Specificity (95% confidence interval)
	Yes	No		
Medium-risk threshold (n=185)				
>40%	58	127	100% (93.8-100%)	0 (0-2.94%)
≤40%	0	0		
>75%	55	88	93.2% (83.8-97.3%)	30.2 (22.8-38.7%)
≤75%	4	38		
>95%	24	29	40.7% (29.1-53.4%)	77.0% (68.9-83.5%)
≤95%	35	97		
Higher-risk threshold (n=35)				
>40%	26	8	100% (87.1-100%)	11.1% (1.99-43.5%)
≤40%	0	1		
>75%	19	2	73.1% (53.9-86.3%)	77.8% (45.3-93.7%)
≤75%	7	7		
>95%	7	0	26.9% (13.7-46.1%)	100% (70.1-100%)
≤95%	19	9		

Discussion

This study has shown a significant strong, positive correlation between TcB and TSB measurements in our local Chinese newborns. The correlation coefficient (r=0.75) was comparable to that reported in a recent study by Taylor et al[6] that involved mainly white or black races (r=0.78), and to a Chinese population in another study (r=0.83)[7].

The TcB measurements overestimated TSB by a mean of 28.76±23.83 μmol/L in our study population. The magnitude of this overestimation was similar to another local study by Ho et al[7] in 2006 (21.7±21.2 μmol/L), but was much larger than that in the study by Taylor et al[6] (14.36±30.44 μmol/L). Nonetheless, a study done on mainly Hispanic neonates showed an underestimation of TSB[13]. This may be due to the difference in race and skin pigmentation. JM-103 Minolta determines the yellowish colour of the subcutaneous tissue and uses a dual optical path system designed to minimise the influence of melanin pigment[14]. It has been suggested that significant differences existed in TcB measurements across populations[15], with a tendency for TcB to underestimate TSB in the lighter skin tone group and to overestimate it in the darker skin tone group[16].

The TcB-TSB difference was associated with the hours of age in some studies in a non-Asian population, but the association was weak[6,13]. TcB-TSB difference did not reveal a significant association with the hours of age in our study. Our study nonetheless demonstrated a significant association between TcB measurements and underestimation of TSB level by ≥20 μmol/L with the hours of age, even though the association was also weak with a regression coefficient of -0.083. The mechanism was not exactly known but changes in haemoglobin concentration in the first days of life were postulated to account for this phenomenon[17].

The use of TcB measurements together with the 75th centile tract of Bhutani nomogram was shown to predict all study cases in the high-risk zone for severe hyperbilirubinaemia (sensitivity=100%) in this cohort. In another study of a Hispanic population in 2004, use of the 75th centile had a lower sensitivity of 71%[13]. Therefore, use of the 75th centile tract of Bhutani nomogram should be able to reduce 25% of unnecessary blood taking, and is associated with less patient suffering and reduced costs. The majority (94.1%) of these newborns in the high-risk zone subsequently required phototherapy. Nonetheless, use of the 75th centile gave a lower sensitivity for predicting the need for phototherapy, especially in higher-risk infants (≥38 weeks with risks or 35-0/7 to 37-6/7 weeks and well Chinese infants) compared with medium-risk infants (≥38 weeks and well), with a sensitivity of 73.1% and 93.2%, respectively. The sensitivity results were lower than in a similar study of Chinese infants by Ho et al[7], in which

the predictive sensitivity for use of the 75th centile was 100% for medium-risk infants and 86.7% for higher-risk infants. Nonetheless, this comparison may not be directly comparable as the study done by Ho et al[7] did not take into consideration Chinese ethnicity as a major risk factor when defining the infant risk level. The advantage of our study is that the thresholds used for phototherapy complied with the latest suggestions by the consensus guideline of the Hospital Authority[11].

There were several limitations of this study. Firstly, most of the paired TcB and TSB levels were taken within the first 3 days of life, as most of the normal newborns in our hospital were discharged by day 3. A higher physiological TSB level would be expected in the later part of the first week of life, especially in our Chinese breastfed newborns. Here we only evaluated the clinical use of TcB measurement in the postnatal ward setting and our finding may not be generalisable to the use of TcB in outpatient newborns. None of our paired samples had TSB levels of >300 μmol/L. The magnitude of TcB measurement overestimation decreases as the TSB level increases with a regression coefficient of -0.382. Further, the TcB measurements tend to be associated with clinically significant underestimation instead of overestimation with increasing TSB level. This finding is consistent with the studies of Taylor et al[6]. Although TcB overestimation provides a safety margin for confirmation and further monitoring, TcB underestimation can potentially result in missing neonates with severe hyperbilirubinaemia. This can cause catastrophic permanent neurological damage as in the case of kernicterus. More caution should be taken and more studies are needed to investigate the accuracy of TcB measurements in babies with more severe jaundice. In addition, although we used the same JM-103 Minolta to take TcB measurements, they were obtained by different operators and this might have introduced error. Third, our neonates were mostly term, healthy, and in the first 3 days of life. The results, conclusions, or recommendations from this study may not be applicable to preterm infants, infants after discharge, or sick infants in SCBU/NICU.

Overall, the TcB value had a high sensitivity and negative predictive value in detecting NNJ in healthy Chinese newborns before discharge from the postnatal ward. Nonetheless, it cannot be considered a substitute for TSB, but rather an effective non-invasive and convenient tool to screen newborns at high risk of significant jaundice. As TcB-TSB differences varied with different TSB levels, caution should be taken especially in cases with severe hyperbilirubinaemia in which TcB measurement tended to underestimate with higher TSB level. The TSB measurements can be reserved for those newborns with TcB level above the 75th centile tract of Bhutani nomogram. Further studies are needed to address the reliability of TcB measurement at high TSB levels that usually occur after discharge. Studies are also needed to evaluate the impact of routine TcB measurement combined with the use of Bhutani nomogram before home discharge on the hospital readmission rate due to high bilirubin level.

Declaration

All authors have disclosed no conflicts of interest.

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Risk Factors for Predicting Blood Transfusion in Caesarean Section in Hong Kong: Is Type and Screen Necessary for All?

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Objective: Routine preoperative blood group typing and antibody screening (type and screen) is performed for all patients who undergo Caesarean delivery in our unit in preparation for blood transfusion. There are no objective local data to support such practice. This study aimed to examine the risk factors for blood transfusion following Caesarean section at a local obstetrics and gynaecology unit in Hong Kong and review the need for universal blood type and screen in patients who underwent Caesarean section.
Methods: This was a retrospective cohort of all deliveries in United Christian Hospital, Hong Kong within a 3-year period from 1 January 2012 to 31 December 2014. Data on demographics, parity, previous Caesarean section/uterine scar, multiple pregnancy, antenatal complications (including anaemia, gestational hypertensive disorders, placenta praevia, placental abruption), and outcomes (postpartum haemorrhage and blood transfusion) were retrieved via the obstetrics clinical information system database.
Results: A total of 119 (3.7%) patients required intraoperative or postoperative transfusion. Univariate analysis showed that the incidence of advanced maternal age, preterm delivery, emergency Caesarean section, multiple pregnancy, as well as presence of placenta praevia and placental abruption were significantly higher in the transfusion group compared with the controls, whereas more patients had previous Caesarean section in the latter group. Multiple pregnancy (odds ratio=3.71), emergency Caesarean section (odds ratio=1.79), placenta praevia (odds ratio=9.64), and placental abruption (odds ratio=6.85) remained statistically significant factors associated with the need for blood transfusion after multivariate regression analysis. A predictive model using these four risk factors gave a sensitivity of 80.6%, specificity of 39%, positive predictive value of 4.8%, and negative predictive value of 98%.
Conclusion: The majority of patients who underwent Caesarean section did not require blood transfusion. Selective type and screen is feasible and safe and can be reserved for patients with specific risk factors.
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Keywords: Blood grouping and crossmatching; Blood transfusion; Cesarean section; Risk factors

Introduction

Caesarean section is one of the most commonly performed obstetric procedures worldwide[1]. It is associated with a higher risk of haemorrhage and blood transfusion than normal vaginal delivery (1-7% vs. 1%)[2]. Blood transfusion is thus a life-saving procedure in obstetrics as severe haemorrhage remains one of the major causes of maternal death[3]. Nonetheless, inappropriate use of blood transfusion can pose potential risks that can be life-threatening because of the potential associated risk of acute or delayed transfusion reactions and complications. Advanced techniques in accurate crossmatching and screening for blood-borne diseases and antibodies of major and minor blood groups are now routinely employed to minimise transfusion complications.

Various risk factors associated with increased blood loss during Caesarean section have been identified in previous studies, and include primiparity, multiple pregnancy, pre-eclampsia, previous Caesarean section, chorioamnionitis, placenta praevia, abnormal presentation (breech or transverse lie), abruptio placentae, pre-existing anaemia, emergency Caesarean section, and Caesarean section under general anaesthesia[4,5]. It has also been shown that the use of blood transfusion associated with Caesarean section has progressively decreased over the decades while the mean estimated blood loss has not significantly changed. In a 30-year observational study, blood transfusion rates dropped from 22% in the 1970s to only 5% in 2006 and this drop was not associated with increased maternal morbidity or mortality[6]. Traditionally, blood type and screen was performed for all patients who underwent

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Caesarean section in our unit, irrespective of whether they were elective or emergency Caesarean sections. With the decreasing need for blood transfusion in Caesarean section, and increasing evidence worldwide that type and screen is not necessary for all Caesarean sections, routine type and screen may no longer be a cost-effective practice[5]. It may place unnecessary pressure on haematology laboratory services of the hospital, particularly in the emergency setting. The present study aimed to review the need to routinely order blood type and screen for all patients who underwent Caesarean section and to explore the risk factors for blood transfusion in Caesarean section in Hong Kong, so as to determine whether type and screen for selected patients only is feasible.

Methods

This retrospective cohort was reviewed over a 3-year period in United Christian Hospital, Hong Kong. Records of all deliveries by Caesarean section from 1 January 2012 to 31 December 2014, whether elective or emergency, were retrieved from the obstetrics clinical information system database and were reviewed. Additional clinical information including demographics, parity, previous Caesarean section/uterine scar, multiple pregnancy, antenatal complications (anaemia, gestational hypertensive disorders, placenta praevia, placental abruption), and outcome (postpartum haemorrhage and blood transfusion rate) was extracted from the labour ward registry, individual clinical notes of patients, and verified with laboratory data including blood bank records.

The primary outcome measure was blood transfusion during the hospital admission for delivery. Postpartum haemorrhage was defined as blood loss of >500 ml and severe postpartum haemorrhage as >1000 ml. Advanced maternal age was defined as ≥35 years at delivery, and preterm delivery was defined as any delivery before 37 complete gestational weeks. Antenatal anaemia was defined as haemoglobin level of <110 g/L at any time during gestation. Pre-eclampsia was defined as proteinuric gestational hypertension after 20 weeks of gestation with blood pressure of ≥140/90 mm Hg on two or more occasions 4 hours apart, or one measurement of systolic over 170 mm Hg or diastolic over 110 mm Hg or in line with the department's protocol. Blood transfusion cases included all with intrapartum transfusions, and transfusions within 72 hours after operation. Univariate analysis was performed to compare demographic characteristics and outcomes of those who required blood transfusion with those who did not. Categorical data were compared using Chi-square and Fisher's exact tests. Multivariate logistic regression was then performed by including all likely factors that would affect the rate of blood transfusion, using presence or absence of blood transfusions, to delineate the significant risk factors. Data analysis was undertaken using the Statistical Package for the Social Sciences Windows version 23 (SPSS Inc., Chicago [IL], US), and a p value of <0.05 was considered statistically significant. Odds ratio (OR) and 95% confidence intervals were reported for individual risk factors.

Results

A total of 13,596 deliveries were carried out within the study period, of which 3212 (23.6%) were Caesarean sections. There were 1463 (45.5%) elective Caesarean sections and 1749 (54.5%) emergency sections. In all, 119 (3.7%) patients required intraoperative transfusion or postoperative transfusion. Within this cohort, the overall incidence of postpartum haemorrhage with blood loss of ≥500 ml was 4.7% (n=151), and the incidence of severe postpartum haemorrhage with blood loss of >1000 ml was 1.8% (n=59). Univariate analysis showed that the incidence of advanced maternal age, preterm delivery, emergency Caesarean section, multiple pregnancy, presence of placenta praevia, and placental abruption were all significantly higher in the transfusion group compared with the controls (Table 1). On the other hand, the incidence of previous Caesarean section was paradoxically lower in the transfusion group, due to the low transfusion rates within the very high proportion of elective repeat Caesarean sections for previous Caesarean section in the cohort (p=0.001). A logistic regression model using the enter technique to delineate the significant factors associated with the need for blood transfusion showed that multiple pregnancy (OR=3.71), emergency Caesarean section (OR=1.79), placenta praevia (OR=9.64), and placental abruption (OR=6.85) remained statistically significant factors associated with the need for blood transfusion (Table 2). Using these four parameters as predictors of the need for blood transfusion gave a sensitivity of 80.6%, specificity of 39%, positive predictive value of 4.8%, and negative predictive value of 98%.

Discussion

In this retrospective study, our blood transfusion rate in Caesarean section was 3.7%, similar to the reported rates in other developed countries (<1-7%)[2,6,7]. Risk factors associated with increased risk of blood transfusion, which included advanced maternal age, preterm delivery, emergency Caesarean section, multiple pregnancy, as well as presence of placenta praevia and placental abruption were similar to other studies worldwide[2,6,8-11]. In other studies,

Table 1. Epidemiological and pregnancy characteristics for patients with and without blood transfusion

	No transfusion (n=3093)	Transfusion (n=119)	p Value	Estimated number needed to treat*
Parity			0.35	
Primiparous	1469 (47.5%)	62 (52.1%)		24
Multiparous	1624 (52.5%)	57 (47.9%)		29
Advanced maternal age (≥35 years)	1290 (41.7%)	61 (51.3%)	0.047	29
Antenatal anaemia (haemoglobin level of <110 g/L)	113 (3.7%)	6 (5.0%)	0.47	11.6
Pre-eclampsia	114 (3.7%)	5 (4.2%)	0.27	24
Preterm delivery of <37 weeks	365 (11.8%)	24 (20.2%)	0.009	16
Type of Caesarean section			0.024	23
Emergency	1675 (54.2%)	77 (64.7%)		
Elective	1418 (45.8%)	42 (35.3%)		
Previous Caesarean section	1309 (42.3%)	32 (26.9%)	0.001	42
Multiple pregnancy	307 (9.9%)	29 (24.4%)	0.001	11.6
Placenta praevia	120 (3.9%)	30 (25.2%)	<0.001	5
Placental abruption	14 (0.5%)	3 (2.5%)	0.023	5.6

* No. of patients with type and screen / No. of patients transfused

Table 2. Multivariate logistic regression model of risk factors for blood transfusion

Factor	Odds ratio (95% confidence interval)	p Value
Parity	1.52 (0.91-2.53)	0.10
Advanced maternal age	1.31 (0.89-1.93)	0.17
Multiple pregnancy	3.71 (2.21-6.23)	0.001
Antenatal anaemia	0.64 (0.27-1.51)	0.31
Previous Caesarean section	0.61 (0.34-1.10)	0.10
Preterm delivery	0.61 (0.35-1.09)	0.09
Emergency Caesarean section	1.79 (1.14-2.82)	0.01
Placenta praevia	9.64 (5.84-15.90)	0.001
Placental abruption	6.85 (1.82-25.81)	0.004

pre-eclampsia and eclampsia were also associated with more blood transfusion[9,10] but this was not observed in our study. It is well established that severe pre-eclampsia can be associated with haemolytic anaemia, thrombocytopenia and coagulopathy, all of which may lead to a bleeding tendency with increased blood loss and increased need for transfusion during delivery. Nonetheless, the failure of our data to identify pre-eclampsia as a risk factor for blood transfusion could be due to the low incidence of severe pre-eclampsia and eclampsia with complications among the 3% to 4% of pre-eclampsia patients in this cohort.

Surprisingly, antenatal anaemia was not a significant risk factor for blood transfusion in our study. Compared with the results from other developed countries, Rouse et al[2] found that even mild anaemia (haematocrit concentration, 25-29%) was a significant risk factor for blood transfusion in the US. Results from Finland (OR=3.38)[6], Australia (OR=6.3)[8], Taiwan (OR=1.78)[9], and India (OR=9.93)[10] have all reported an increased risk of transfusion. The definition of antenatal anaemia in our study (<110 g/L) did not differ to others, but the incidence of severe anaemia may differ in different obstetric populations. The effects of anaemia on risk of blood transfusion in Caesarean section could be more marked in developing countries due to an increased prevalence of iron deficiency anaemia and lack of

antenatal surveillance or antenatal management to correct the anaemia. Another possible explanation for the observed difference in this cohort could be that haemoglobin after Caesarean section was only checked when there was significant blood loss or if the patient had symptoms of anaemia in the postnatal period. Nonetheless, even if mild anaemia was detected incidentally in the early postpartum period, top-up transfusion was not usually required unless the patient was symptomatic, so the impact on transfusion rates would probably be small.

Placenta praevia is known to be associated with increased risk of severe postpartum haemorrhage, ranging from 1.3% to 25.8% for singleton deliveries[12,13]. The need for blood transfusion may be used as a marker of the severity of haemorrhage. Of 150 patients with placenta praevia who underwent Caesarean section in this cohort, 30 required blood transfusion, so that the transfusion rate for placenta praevia was 20%. Even after multivariate regression analysis, placenta praevia remained the most significant factor for blood transfusion (OR=9.64). Specific high risk factors for severe haemorrhage could be identified in cases of placenta praevia and would indicate the highest risk for intraoperative blood transfusion, including placenta covering a previous Caesarean scar, previous Caesarean section, and lacunae on ultrasound suggestive of placenta accreta[14]. Careful preoperative ultrasound evaluation of all cases of placenta praevia is advisable to detect any of the possible features and, if present, a crossmatch with blood products available in the operating theatre may be warranted instead of just a type and screen.

Apart from placenta praevia, three other significant risk factors were identified after multivariate logistic regression analysis: multiple pregnancy, emergency Caesarean section, and placental abruption. It is well established that placental abruption can be associated with coagulopathy and thus increased risks for transfusion[15], while both multiple pregnancy and emergency Caesarean section have been associated with postpartum haemorrhage due to uterine atony[16]. Similar models have been reported in the literature and the risk factors identified are similar to the present study[17].

In this study, a model for predicting the need for blood transfusion and thus the need for preoperative type and screen can be produced using these four parameters, and gave a sensitivity of 80.6%, specificity of 39%, positive predictive value of 4.8%, and negative predictive value of 98%. Thus, restricting routine type and screen to patients who are going to undergo Caesarean section with these four significant factors can identify around 80% of patients who truly require a blood transfusion in Caesarean section. On the contrary, applying its negative predictive value for clinical use, patients who do not have any of these four risk factors would have 98% chance that a blood transfusion is not required and hence preoperative type and screen can probably be safely omitted.

There are no local data available on risk factors for blood transfusion in Caesarean section, nor is there any solid evidence for the efficacy of routine type and screen for every patient who undergoes Caesarean section in Hong Kong. Our data confirmed that most patients who undergo Caesarean section do not require a transfusion and provide preliminary evidence that selective type and screen is actually feasible and safe for low-risk patients who undergo Caesarean section and who have no specific risk factors for transfusion. Further prospective region-wide studies may be necessary to provide better evidence-based preoperative type and screen protocols for Caesarean section in Hong Kong to verify its effectiveness and safety. There should be contingencies in haematology laboratories to support each obstetric service to provide rapid crossmatching for emergency blood transfusion needs. Nonetheless, the screening model using the four predictive factors: multiple pregnancy, emergency Caesarean section, placenta praevia, and placental abruption can be easily applied in both elective and emergency settings to determine patients who require a routine type and screen before Caesarean section to reduce unnecessary work for the laboratory.

Declaration

The authors have disclosed no conflicts of interest.

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Vault Haematoma following Hysterectomy: Three-year Experience

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Objectives: To examine the incidence of vault haematoma following different types of hysterectomy and to identify any risk factors related to its occurrence.
Methods: This was a retrospective analysis of patients with vault haematoma over a 3-year period (January 2012 to December 2014) at the Department of Obstetrics and Gynaecology of Pamela Youde Nethersole Eastern Hospital, Hong Kong. A total of 801 hysterectomies were performed during the above period and 56 vault haematomas were identified. Five cases of laparoscopic-assisted supracervical hysterectomy and subtotal hysterectomy were excluded.
Results: The overall incidence of symptomatic vault haematoma was 7.04%. The occurrence of vault haematoma was associated with route of hysterectomy (p=0.03). Among routes of hysterectomy, vaginal hysterectomy was significantly associated with vault haematoma (p=0.004). Patient factors were not associated with occurrence of vault haematoma, which included taking antiplatelet agents (p=0.99) or anticoagulants (p=0.19) that were related to a bleeding tendency, a history of diabetes mellitus (p=0.81) or menopausal status (p=0.18) that could influence wound healing ability, parity (p=0.51), history of lower segment Caesarean section (p=0.65), and uterine size (p=0.72) that could affect degree of difficulty of operation.
Conclusion: Vaginal hysterectomy is more likely to be associated with occurrence of vault haematoma than hysterectomy performed via other routes. It is important to consider the possibility of vault haematoma in patients with persistent fever and vaginal bleeding after vaginal hysterectomy. No other definite risk factors were identified in this study.
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Keywords: Hematoma; Hysterectomy; Risk factors

Introduction

Hysterectomy is the most common major gynaecological procedure. Postoperative vault haematoma is known to be associated with higher morbidity and longer recovery. A review showed that the presence of postoperative vault haematoma is associated with increased febrile morbidity and other morbid factors, e.g. need for blood transfusion, a greater drop in haemoglobin level, longer length of postoperative hospital stay, and greater number of readmissions[1]. Nonetheless, data on the incidence of vault haematoma after different types of hysterectomy are scarce. The incidence of vault hematoma after vaginal hysterectomy (VH) is apparently better studied than following other types of hysterectomy, but the literature reports a wide range of incidence varying from 19.4% to 98%[2,3]. According to the review by Thomson and Farquharson[1], bleeding tendency or difficulty achieving haemostasis during surgery may contribute to formation of haematoma after hysterectomy. There is a need to identify the risk factors for vault haematoma in order to minimise its occurrence. A local retrospective review of experience in laparoscopic-assisted vaginal hysterectomy (LAVH) reported the rate of vault haematoma to be 31.0%[4]. A retrospective review of vaginal hysterectomies in the absence of uterine prolapse showed a significant decrease in rate of vault haematoma from 12% to 1% (p=0.002) in the second study period[5]. The authors[5] suggested that surgeon experience was an important factor in occurrence of vault haematoma: paying particular attention to potential bleeders during operation was especially important. To the best of our knowledge, no study has examined the incidence and risk factors related to patient characteristics associated with the formation of vault haematoma.

This study aimed to examine the incidence of vault haematoma following hysterectomies performed via different routes to determine whether there is an association between route and incidence of vault haematoma, and to identify any patient risk factors for vault haematoma.

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Methods

This was a retrospective analysis of patients with vault haematoma over a 3-year period (January 2012 to December 2014) at the Department of Obstetrics and Gynaecology of Pamela Youde Nethersole Eastern Hospital, Hong Kong.

Electronic records and medical records that included operation notes, ultrasound records, and progress notes of 801 women who underwent hysterectomy were reviewed through the hospital's Clinical Management System and Operating Theatre Management System. All patients with an ultrasound record showing vault haematoma were included. Vault haematoma was defined as a non-peristaltic complex echogenic mass on ultrasound[2]. Those with an intra-abdominal haematoma instead of vault haematoma diagnosed by more advanced imaging modality were excluded. Ultrasound examination to look for vault haematoma was performed postoperatively when clinically indicated, in accordance with our protocol. Ten types of hysterectomy were performed during the study period: total abdominal hysterectomy (TAH, n=449), VH (n=100), LAVH (n=22), subtotal hysterectomy (STH, n=3), radical abdominal hysterectomy (RAH, n=3), Wertheim's hysterectomy (WH, n=4), total laparoscopic hysterectomy (TLH, n=122), laparoscopic-assisted supracervical hysterectomy (LA supracervical hysterectomy, n=2), robotic-assisted total laparoscopic hysterectomy (RATLH, n=89), and robotic-assisted radical hysterectomy (RA radical hysterectomy, n=7). The five hysterectomies that were excluded in this study were STH and LA supracervical hysterectomy, as the cervix was not removed in these surgeries. A total of 56 cases of vault haematoma in 796 patients were identified. They were divided into five groups according to the route of hysterectomy, including abdominal, VH, LAVH, robotic-assisted and laparoscopic-assisted, to determine whether route of hysterectomy was associated with occurrence of vault haematoma (Table 1). The patients were further divided into those with and without vault haematoma to identify other patient risk factors for vault haematoma. The characteristics examined included menopausal status, parity, use of antiplatelet agents (e.g. aspirin and plavix) or anticoagulants (e.g. warfarin), presence of diabetes mellitus (DM), and uterine size. For DM, we included those with a history of DM who were prescribed either oral hypoglycaemic agents or insulin.

Demographic data extracted from the medical records for those with vault haematoma included age, body mass index (BMI), obstetric history, menopausal status, and indication for surgery. To gauge the potential risk factors influencing the formation of vault haematoma, the following data were extracted:

1. operation notes for duration of surgery, choice of antibiotic prophylaxis, and blood loss;
2. perioperative morbidities and length of hospital stay;
3. the rate of readmission and the reason;
4. the symptom(s) for which ultrasound was performed to look for vault haematoma;
5. the size of the vault haematoma on transvaginal ultrasound; and
6. the management of the vault haematoma.

Data were entered into Microsoft Excel and analysed using the Statistical Package for the Social Sciences Windows version 23 (SPSS Inc., Chicago [IL], US). Chi-square test was used to determine any association between various factors and occurrence of vault haematoma. In assessing the association between the route of hysterectomy with vault haematoma, TAH, RAH, and WH were pooled together as these three routes of hysterectomy were via an abdominal approach. RATLH and RA radical hysterectomy were pooled together as these two routes involved robotic

Table 1. Routes of hysterectomy (n=796)

Route	Vault haematoma	No vault haematoma
Abdominal (TAH, WH, radical abdominal hysterectomy) [n=456]	27 (5.9%)	429 (94.1%)
VH (n=100)	14 (14%)	86 (86%)
LAVH (n=22)	0	22 (100%)
Robotic-assisted (RATLH, RA radical hysterectomy) [n=96]	8 (8.3%)	88 (91.7%)
TLH [n=122]	7 (5.7%)	115 (94.3%)
Total	**56 (7.0%)**	**740 (93.0%)**

Abbreviations: LAVH = laparoscopic-assisted vaginal hysterectomy; RATLH = robotic-assisted total laparoscopic hysterectomy; TAH = total abdominal hysterectomy; TLH = total laparoscopic hysterectomy; VH = vaginal hysterectomy; WH = Wertheim's hysterectomy

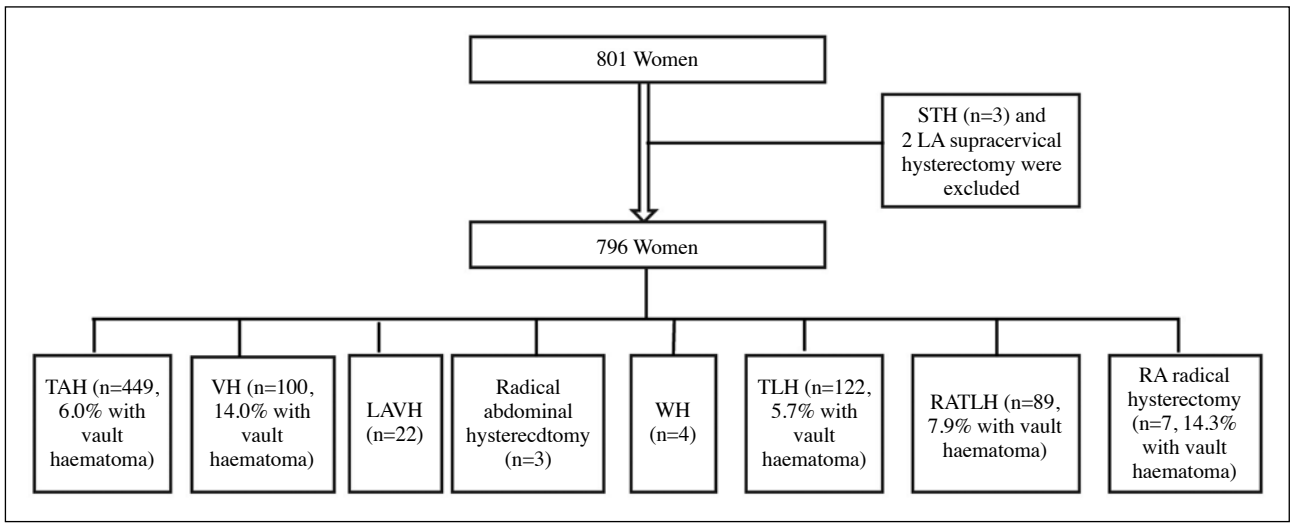

Figure 1. Flowchart showing various types of hysterectomy for study subjects and those with vault haematoma

Abbreviations: LA supracervical hysterectomy = laparoscopic-assisted supracervical hysterectomy; LAVH = laparoscopic-assisted vaginal hysterectomy; RA radical hysterectomy = robotic-assisted radical hysterectomy; RAH = radical abdominal hysterectomy; RATLH = robotic-assisted total laparoscopic hysterectomy; STH = subtotal hysterectomy; TAH = total abdominal hysterectomy; TLH = total laparoscopic hysterectomy; VH = vaginal hysterectomy; WH = Wertheim's hysterectomy

assistance. Student's *t* test was used to assess presence of association between uterine size and occurrence of vault haematoma. A p value <0.05 was considered statistically significant. This study was approved by the Hong Kong East Cluster Ethics Committee and conducted in full compliance with the International Council for Harmonisation E6 Good Clinical Practice and the Declaration of Helsinki.

Results

Among 796 hysterectomies, 56 cases of vault haematoma were documented, giving an overall incidence of 7.04%. Vault haematoma was found in TAH (27/449, 6.0%), VH (14/100, 14.0%), TLH (7/122, 5.7%), RA radical hysterectomy (1/7, 14.3%), and RATLH (7/89, 7.9%) [Figure 1]. The vault was closed by intracorporeal continuous suture Vicryl O (Ethicon, Mexico) in all laparoscopic hysterectomies, including TLH, RATLH, and RA radical hysterectomies. All VHs were performed for genital prolapse. The route of hysterectomy was significantly associated with occurrence of vault haematoma (p=0.03). Subgroup analysis revealed that VH was significantly associated with the occurrence of vault haematoma among the five routes of hysterectomy (p=0.004). The indications for hysterectomies complicated by vault haematoma are shown in Table 2. Most were performed for a benign condition.

The details of operations complicated by vault haematoma are shown in Table 3. The shortest time in surgery was for a patient undergoing VH for genital prolapse, the longest for a patient undergoing TAH and staging for carcinoma of the cervix complicated by ureteric injury requiring psoas hitch for repair. The minimal blood loss of 10 ml was in a case of RA radical hysterectomy for carcinoma of the cervix. The maximum blood loss of 3200 ml was following TAH for fibroid. All patients were prescribed antibiotic prophylaxis, in most cases cefazolin, a broad-spectrum, first-generation cephalosporin. Other

Table 2. Indications for hysterectomies complicated by vault haematoma (n=56)

Indication	No. of patients
Benign (n=43)	
Fibroid	22
Adenomyosis	4
Ovarian cyst	2
Genital prolapse	14
Abnormal pap smear	1
Premalignant (n=6)	
Atypical complex hyperplasia	6
Malignant (n=7)	
CA corpus	4
CA cervix	1
CA ovary	2

Abbreviation: CA = carcinoma

factors influencing the choice of antibiotic prophylaxis included a history of drug allergy and preference of the chief surgeon who made the final choice.

Among the 56 cases of vault haematoma, 14 (25%) required blood transfusion during or after surgery, and two (3.6%) required transfusion of other blood products such as platelets or fresh frozen plasma. Of these patients who required transfusion, 11 had undergone TAH, two had VH, and one had RATLH.

The length of postoperative hospital stay in this group ranged from 3 to 15 days. Two patients had the longest hospital stay of 15 days, including the first patient undergoing RA radical hysterectomy and pelvic lymph node dissection for carcinoma of cervix, and the second undergoing TAH and bilateral salpingo-ophorectomy, pelvic lymph node and para-aortic lymph node dissection for carcinoma of corpus. In both patients, the postoperative period was complicated by postoperative fever requiring intravenous antibiotics.

Table 3. Details of hysterectomies complicated by vault haematoma (n=56)

	Data
Mean (range) duration of operation (mins)	142 (45-426)
Mean (range) blood loss (ml)	393 (10-3200)
Antibiotic prophylaxis	
Cefazolin	52 (92.9%)
Augmentin	2 (3.6%)
Clindamycin	1 (1.8%)
Rocephin	1 (1.8%)
Blood transfusion	14 (25%)
Blood product transfusion	2 (3.6%)
Mean (range) duration of postoperative hospital stay (days)	6.3 (3-15)

The diagnosis of vault haematoma on ultrasound was made from postoperative day 2 to day 40 (Figure 2). Vault haematoma was diagnosed within 5 days of surgery in one third of the patients.

Comparison of baseline characteristics of patients with or without vault haematoma is shown in Table 4. With regard to patient factors related to bleeding tendency or ease of haemostasis during operation, neither use of antiplatelet agents nor anticoagulants was associated with occurrence of vault haematoma (p=0.99 and p=0.19, respectively). With respect to factors influencing wound healing ability, neither a history of DM (p=0.81) nor menopausal status (p=0.18) was associated with occurrence of vault haematoma. For

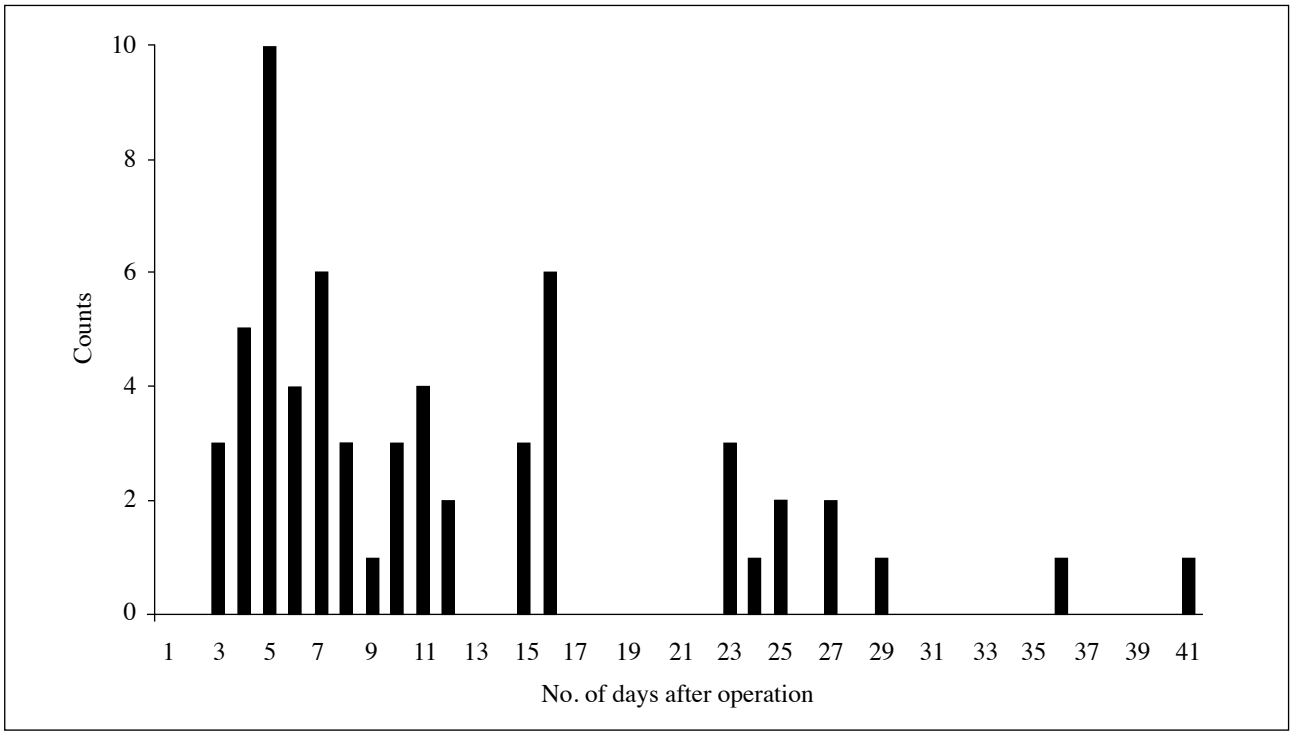

Figure 2. Time of diagnosis of symptomatic vault haematoma

Table 4. Comparison of patient characteristics in those with or without vault haematoma

	Vault haematoma (n=56)	No vault haematoma (n=740)	p Value
Mean (±SD, range) age (years)	52.75 (11.67, 33-77)	54.25 (10.85, 29-93)	0.47
Menopausal state (%)	18 (32.1%)	306 (41.4%)	0.18
Mean (range) parity	1.75 (0-5)	1.69 (0-10)	-
Grand multiparity ≥3	15 (26.8%)	169 (22.8%)	0.51
History of LSCS	8 (14.3%)	90 (12.2%)	0.65
Mean (range, 95% CI) uterine size (weeks)	10.1 (4-24, -1.33 to 1.95)	10.4 (0-36, -1.39 to 2.00)	0.72
History of diabetes mellitus	6 (10.7%)	87 (11.8%)	0.81
Antiplatelet agent	3 (5.4%)	40 (5.4%)	0.99
Anticoagulant	2 (3.6%)	10 (1.4%)	0.19

Abbreviations: 95% CI = 95% confidence interval; LSCS = lower segment Caesarean section; SD = standard deviation

BMI, the statistical analysis was aborted as data were missing in 32.1% of the 56 cases with vault haematoma. In examining factors related to ease of operation such as parity, patients were further divided into grand multiparity or not: parity was not associated with occurrence of vault haematoma (p=0.51). History of lower segment Caesarean section (LSCS) was not associated with occurrence of vault haematoma (p=0.65). Size of uterus was related to ease of operation but across all routes of hysterectomy showed no association with vault haematoma (p=0.72). Subgroup analysis also did not show any statistically significant difference in uterine size between patients with or without vault haematoma after VH (mean [±standard deviation] uterine size, 4.86±6.24 weeks vs. 5.56±5.95 weeks; p=0.22).

The main patient factors that prompted ultrasound examination to determine occurrence of vault haematoma are shown in Table 5. Postoperative fever was defined as presence of temperature >37.8°C for more than 24 hours. Among patients with vault haematoma, the most common presenting symptom was postoperative pyrexia (51.8%) followed by vaginal bleeding (28.6%). Other presentations included acute retention of urine (7.1%), other urinary symptoms like incomplete emptying or incontinence (5.4%), abdominal pain (3.6%), vaginal discharge (1.8%), and drop in haemoglobin (1.8%). Readmission for management of vault haematoma was required by 26 patients.

Treatment of vault haematoma (Table 5) with oral antibiotics alone resulted in resolution of vault haematoma in 55.3% of cases, but both drainage and intravenous antibiotics were required in three cases. The first patient had undergone VH and repair of cystocoele for genital prolapse. Transvaginal and transabdominal ultrasound was performed on postoperative day 2 when haemoglobin had fallen to 4.4 g/dl and revealed a vault haematoma of 267.59 ml. The second patient had TAH performed for fibroid and was readmitted with fever. Transvaginal and transabdominal ultrasound performed on postoperative day 8 revealed a vault haematoma of 32.75 ml. The third patient had TAH done for right broad ligament fibroid; transvaginal and transabdominal ultrasound on day 2 after operation for fever revealed a vault haematoma of 151.85 ml. All three

Table 5. Presentation and management of vault haematoma (n=56)

	Chief complaint
Presentation	
Vaginal bleeding	16 (28.6%)
Fever	29 (51.8%)
Vaginal discharge	1 (1.8%)
Abdominal pain	2 (3.6%)
Acute retention of urine	4 (7.1%)
Urinary symptoms	3 (5.4%)
Drop in haemoglobin	1 (1.8%)
Readmission	26 (46.4%)
Management	
Oral antibiotics alone	31 (55.3%)
Intravenous antibiotics ± oral antibiotics	24 (42.9%)
Drainage and intravenous antibiotics	3 (5.4%)
No treatment	1 (1.8%)

patients were prescribed antibiotics as first-line treatment, and drainage was subsequently performed when fever persisted beyond 5 days of intravenous antibiotics. Two patients required haematoma drainage by Foley catheter and one was drained by pipelle.

Volume of the vault haematoma was calculated from three dimensions. Data were incomplete in eight of the 56 cases who had only two dimensions recorded on the ultrasound report. They were excluded from analysis. Of the remaining 48 patients, vault haematoma volume was ≥20 ml in 22 and <20 ml in 26. Among those with vault haematoma ≥20 ml, the volume ranged from 20.64 ml to 267.59 ml. Among the three patients who required drainage, two had the largest volume of vault haematoma among those ≥20 ml.

Discussion

The overall incidence of vault haematoma in this study was 7.04%, far lower than that reported by other studies (19.4-98%)[2,3]. One possible explanation is that our incidence reflects the true incidence of symptomatic vault haematoma. Kulkarni and Vijaya[6] suggested that asymptomatic vault haematoma could be diagnosed in the early postoperative period and would subsequently resolve without ever becoming symptomatic. Therefore, our incidence reflects the incidence of vault haematoma that required clinical attention and management.

In the current study, the incidence of vault haematoma was highest following RA radical hysterectomy and VH compared with other types of hysterectomy (14.3% and 14.0%, respectively). Vault haematoma is the most common complication of vaginal hysterectomy[7]; therefore the incidence was expected to be highest in VHs. The incidence was comparable with that reported by Cheung and Pun[5] in their first study period (12%) but was higher than that in their second study period (1%). This may be due to the use of gonadotropin-releasing hormone agonist (GnRHa) in their second study period and not given to our patients prior to VH. The incidence of vault haematoma after RA radical hysterectomy was high but the sample size was small and might not reflect the true incidence. The incidence of vault haematoma after TAH (6.0%) was similar to TLH (5.7%) and RATLH (7.9%) as shown in the current study. Rosen and Cario[8] suggested that the incidence of vault haematoma after TLH is comparable to that after TAH as the laparoscopic approach provides a magnified view of vault anatomy and enables precise haemostasis to avoid formation of vault haematoma. The incidence of vault haematoma after LAVH was 0%, far lower than that reported by Yuen and Rogers[4] (31%) as this study also included patients who were asymptomatic. Furthermore, the study[4] was carried out in the early 1990s, and advances in the design of instruments used for haemostasis in laparoscopic surgery in recent decades could have led to a reduction in vault haematoma.

The current study showed that the route of hysterectomy was associated with the occurrence of vault haematoma and only VH was associated with the occurrence of vault haematoma. Wood et al[9] suggested that the vaginal vault is the most frequent site of bleeding after VH. Due to limited access and poor visualisation during surgery, haemostasis is difficult in VH with consequent formation of vault haematoma.

An interesting observation in the current study was the timing of vault haematoma diagnosis: longest time from hysterectomy to presentation of vault haematoma was 40 days. This implies that vault haematoma can persist long after operation and takes time to resolve if no treatment is given. This justifies a need for timely diagnosis and treatment.

A vault haematoma consists of a collection of blood at the vault after hysterectomy and presumably forms as a result of residual bleeding at the end of surgery. It can be postulated that patient factors that increase bleeding tendency or increase difficulty of haemostasis during operation may be associated with the occurrence of vault haematoma. Surprisingly, the current study showed that vault haematoma was not associated with parity, history of LSCS, menopausal status, use of antiplatelet agents and anticoagulants, or a history of DM. In patients prescribed antiplatelet agents or anticoagulants, we usually take extra precautions for haemostasis and withhold the drugs prior to operation. This may explain the lack of an association of use of antiplatelet agents and anticoagulants with formation of vault haematoma. The same may also apply to patients with a history of LSCS, as surgeons usually take extra precautions in these patients to achieve meticulous haemostasis during operation. DM is known to be associated with poor wound healing but the association with bleeding tendency is not well established. Hence, no association was found between history of DM and formation of vault haematoma in the current study. Finally, the current study was a retrospective study that focused on symptomatic vault haematoma; asymptomatic vault haematoma associated with these risk factors would not have been detected or included.

The review by Cheung and Pun[5] found that uterine

size (in weeks) was statistically different in their two study periods (p≤0.001) but not the uterine weight (p=0.308). The median uterine size was larger in the first study period than the second with a lower incidence of vault haematoma noted in the latter. The study showed an inverse relationship between uterine size and the incidence of vault haematoma over the two study periods[5]. The authors attributed this observation to the use of GnRHa in the second study period. In this study, we directly analysed uterine size and found no association between uterine size and occurrence of vault haematoma across all routes of hysterectomy or after VH. It may be interesting to study the preoperative use of GnRHa in other routes of hysterectomy with occurrence of vault haematoma in future studies.

Cheung and Pun[5] also suggested that surgeon experience was important in the formation of vault haematoma after VH. This was not studied in the current study as we included all routes of hysterectomy that required different levels of surgical expertise. Owing to the retrospective nature of the study, data about the number of same procedures performed by the same surgeon were lacking. Therefore, it may be better to repeat the study and examine surgeon factors in formation of vault haematoma following specific routes of hysterectomy performed by the same group of surgeons.

A prospective observational study by Dane et al[2] suggested that febrile morbidity occurred more in cases with vault haematoma after VH, affecting up to 40% of such patients. This was comparable to the findings of the current study wherein 51.8% of patients with vault haematoma had febrile morbidity. Batish et al[7] suggested that patients with vault haematoma may present with postoperative vaginal bleeding, abdominal distension, paralytic ileus, fever, foul smelling discharge, tenesmus, and abscess formation. The current study showed that those with vault haematoma mostly presented with fever and vaginal bleeding. Thomson et al[10] suggested that 25.5% of patients with vault haematoma after vaginal hysterectomy were readmitted. The readmission rate was higher in the current study. We usually aim for early discharge to achieve an enhanced recovery pathway but the readmission rate is thus expected to be higher. For unexplained fever after hysterectomy, vault haematoma should be at the top of the differential list to be excluded.

There is a complete lack of literature comparing the management of vault haematoma[1]. In this study, the mainstay treatment was oral antibiotics alone (55.3%), an evidence that a trial of oral antibiotics may be sufficient to treat most symptomatic vault haematomas. Nonetheless, drainage of vault haematoma may be necessary under some circumstances, such as larger vault haematoma (≥20 ml)[1]. Drainage can be done using a Foley catheter or pipelle, and further study will be needed to assess the efficacy of both tools.

There were several limitations in this study. Firstly, there was a lack of a universally accepted protocol on management of vault haematoma and the plan of management was at the discretion of the gynaecologist providing postoperative care or the admitting gynaecologist. Second, the retrospective nature of this study prevented randomisation of patients. Third, the missing data due to the retrospective nature of the study limited accurate statistical analysis of the risk factors. Last but not least, the low incidence of symptomatic vault haematoma requires a larger study population to assess the clinical significance of factors, such as the size of vault haematoma and the morbidities. In the last few years, there has been a shift in trend of hysterectomy to laparoscopic surgery. A larger study population cannot be obtained through a longer study period as the sample size will be more heterogeneous. Therefore, a larger sample size can be better achieved with a multicentre study.

Conclusion

The overall incidence of vault haematoma in this study population was 7.04%. The route of hysterectomy was significantly associated with occurrence of vault haematoma (p=0.03), notably VH (p=0.004). Patient characteristics such as parity, history of LSCS, uterine size, menopausal status, use of antiplatelet agents or anticoagulants, and a history of DM were not associated with the occurrence of vault haematoma. As VH is the preferred route of hysterectomy in gynaecological surgery, it is important to consider the possibility of vault haematoma in patients with persistent fever or vaginal bleeding after VH.

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Declaration

No potential conflict of interest relevant to this article was declared.

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Factors of a Mother's Postnatal Decision about Infant Feeding and the Sustainability of Breastfeeding

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Objective: The benefits of breastfeeding to both infants and mothers are widely recognised. Nonetheless, about one third of mothers have stopped breastfeeding upon discharge from our hospital despite the fact that they elected to breastfeed before delivery. This study aimed to examine factors affecting mothers' postnatal decision about infant feeding and sustainability of breastfeeding.
Methods: This was a prospective study using a questionnaire to collect the subjective information from all mothers who were Chinese and who delivered in our hospital from March to April 2015. As maternal factors alone can only partially predict a mother's decision to breastfeed, a thorough exploration of other variables was also performed.
Results: Analysis of the 172 questionnaires returned revealed that maternal intention to breastfeed correlated with initiation of skin-to-skin contact in the labour ward (odds ratio=2.1, 95% confidence interval, 0.97-4.60; p=0.046) and the presence of the husband during labour (odds ratio=2.3, 95% confidence interval, 0.97-5.51; p=0.048).
Conclusion: Skin-to-skin contact and presence of the husband during labour should be promoted and advocated. These factors are also important for us to develop promotional policies and provide effective counselling in order to improve the breastfeeding rate and sustain a longer duration of breastfeeding.
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Keywords: Breast feeding; Infant; Maternal behaviour; Mother-Child Relations; Spouses

Introduction

Breastfeeding is universally acknowledged as the first step in the promotion of health and wellbeing of children and their family. The benefits of breastfeeding to both the infant and the mother are widely recognised[1] and the health risks associated with infant formula feeding are increasingly documented[1-4]. Women in Hong Kong increasingly choose to breastfeed their infants[5]. In order to understand the prevalence of breastfeeding and the sustainability of breastfeeding among the mother-infant dyads who deliver in Hospital Authority (HA) birthing hospitals, the Hospital Authority Breastfeeding Promotion Subcommittee (HABFPSC) has conducted annual surveys in March since 1999. The mean breastfeeding rate upon discharge from the HA maternity units increased from 57.6% in 2005 to 81.8% in 2014 (according to a report on "Breastfeeding—Postnatal Survey in Obstetric Department" by HABFPSC). Nonetheless, in our hospital, the breastfeeding rate upon discharge was lower in March 2014 at 77.2%.

According to the annual statistics from our hospital, the mean breastfeeding rate upon discharge from 2008 to 2013 was 71.2%, 74.1%, 75.5%, 69.9%, 69.1% and 69.5%, respectively. In 2013, 81.6% of mothers opted for breastfeeding prior to delivery, but the rate dropped to 69.5% following discharge. In view of the unsatisfactory results, some changes were implemented in our unit to improve the breastfeeding rate upon discharge. First, skin-to-skin contact was initiated immediately after birth in the delivery suite. Second, assistance was given to mothers in the postnatal ward to express breast milk for babies in the special care baby unit or neonatal intensive care unit. Third, better support for postnatal mothers was offered; for instance, nursing pillows and a footstool were provided, mothers were taught before discharge how to perform manual expression, and baby models and breast models were used for demonstration. Lastly, a trained peer support group was organised to assist and support breastfeeding mothers in the postnatal ward.

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After implementation of these measures, the breastfeeding rate had increased to 77.2% in March 2014. Nonetheless, the breastfeeding rate upon discharge did not reveal the percentage of mothers who changed their mode of infant feeding during admission and that could have been from bottle feeding to exclusive breastfeeding/mixed feeding or vice versa. An earlier survey was conducted from June to July 2014 to determine how many mothers changed their mind about mode of infant feeding.

The questionnaires were distributed and collected after the postnatal talk and before discharge from hospital. Of the 409 questionnaires returned, 27 had missing data and were excluded from the study. Among the remaining 382 questionnaires, 301 (78.8%) and 51 (13.4%) of the mothers did not change their decision about breastfeeding/mixed feeding and artificial feeding respectively. Nonetheless, a further 18 (4.7%) and 12 (3.1%) mothers had changed from breastfeeding to artificial feeding and from artificial feeding to breastfeeding/mixed feeding, respectively. In order to identify factors that influence a mother's postnatal decision about mode of infant feeding and affect the sustainability of breastfeeding after discharge, a study was designed and ethics approval granted by the Research Ethics Committee of Kowloon West Cluster [Reference No.: Kw/EX-15-013 (83-14)].

Methods

A prospective hospital-based cohort questionnaire study was conducted from March to April 2015. In order to obtain more subjective information, the questionnaires were revised based on the findings of the previous survey conducted in 2014. All mothers who were Chinese and who delivered in our hospital during the study period were recruited. Any non-Chinese mothers who could not read or write Chinese were excluded. If the mother did not agree to participate in this study, her subsequent care and treatment would not be affected. Informed written consent was obtained from all participants.

The questionnaires were distributed after the postnatal talk and collected before discharge from hospital. As maternal factors alone can only partially predict a woman's decision to breastfeed, a thorough exploration of other variables is warranted. These variables were retrieved from the clinical record and included demographic data, labour process, mode of delivery, presence or absence of husband, use of pharmacological or non-pharmacological pain relief, skin-to-skin contact initiated on the labour ward, and whether baby was separated from the mother or in same room. For those mothers who agreed to have follow-up by phone call, they were contacted 4 to 5 weeks after delivery to enquire about the mode of infant feeding.

Results

Of the 172 questionnaires returned, 136 (79.0%) and 27 (15.7%) of the mothers did not change their decision about breastfeeding/mixed feeding and artificial feeding respectively. Nonetheless, five (2.9%) and four (2.3%) of the mothers changed from breastfeeding to artificial feeding and from artificial feeding to breastfeeding/mixed feeding respectively (Table 1). Overall, 140 mothers had chosen breastfeeding or mixed feeding upon discharge. The reasons included: beneficial to her baby (82.3%), beneficial to herself (77.3%), having family support (34.8%), natural food for baby (29.8%), and having support from hospital staff (26.2%). On the contrary, 32 mothers had chosen artificial feeding upon discharge. The reasons were insufficient confidence (30.0%), fatigue after delivery (26.7%), insufficient milk (23.3%), and wound pain (13.3%).

Maternal age, gestational age at delivery, mode of delivery, and use of oxytocin or pethidine did not show any significant effect on intention to breastfeed during the hospital stay (Table 2). As 19 mothers could not be contacted by phone for follow-up at 4 to 5 weeks post-delivery, 153 mothers were included in the final cohort. Statistical analysis also showed that the above intrapartum factors did not affect maternal decision.

Maternal intention to breastfeed has been shown to be strongly correlated with the initiation and duration of breastfeeding[5-8]. Our data showed that maternal intention to breastfeed was correlated with the initiation of skin-to-skin contact in the labour ward (odds ratio [OR]=2.1, 95% confidence interval [CI], 0.97-4.60; p=0.046) and the presence of their husband during labour (OR=2.3, 95% CI, 0.97-5.51; p=0.048) [Table 2]. These two factors were also significantly correlated with sustained breastfeeding

Table 1. Change to mothers' decision about mode of infant feeding before birth and upon discharge from hospital (n=172)

Type	No. (%)
Breastfeeding (no change)	105 (61.0)
Artificial feeding (no change)	27 (15.7)
Breastfeeding to mixed feeding	31 (18.0)
Breastfeeding to artificial feeding	5 (2.9)
Artificial feeding to breastfeeding/mixed feeding	4 (2.3)

Table 2. Relationship between mothers' choice of mode of infant feeding upon discharge with maternal and intrapartum factors*

	Breastfeeding/mixed feeding (n=140)	Artificial feeding (n=32)	p Value	Odds ratio (95% confidence interval)
Maternal age (years)			0.624	-
≤19	1 (0.6)	0		
20-34	89 (51.7)	23 (13.4)		
≥35	50 (29.1)	9 (5.2)		
Preterm at delivery	10 (5.8)	2 (1.2)	0.608	-
Primiparous	77 (44.8)	15 (8.7)	0.262	-
Use of oxytocin	40 (23.3)	8 (4.7)	0.355	-
Use of pethidine	46 (26.7)	12 (7.0)	0.131	-
Caesarean section	26 (15.1)	8 (4.7)	0.281	-
Husband accompanying labour	61 (35.5)	8 (4.7)	0.048	2.3 (0.97-5.51)
Skin-to-skin contact	95 (55.2)	16 (9.3)	0.046	2.1 (0.97-4.60)

* Data are shown as No. (%) of women, unless otherwise specified

Table 3. Relationship between mothers' choice of mode of infant feeding at 4 weeks after delivery with maternal and intrapartum factors*

	Breastfeeding/mixed feeding (n=106)	Artificial feeding (n=47)	p Value	Odds ratio (95% confidence interval)
Use of oxytocin	38 (24.8)	15 (9.8)	0.355	-
Use of pethidine	45 (29.4)	14 (9.2)	0.131	-
Caesarean section	19 (12.4)	13 (8.5)	0.126	-
Husband accompanying labour	51 (33.1)	13 (8.5)	0.014	2.5 (1.19-5.24)
Skin-to-skin contact	74 (48.4)	23 (15.0)	0.009	2.5 (1.25-5.07)

* Data are shown as No. (%) of women, unless otherwise specified

at 4 weeks post-delivery (initiation of skin-to-skin contact in labour ward: OR [95% CI], 2.5 [1.25-5.07]; p=0.009); presence of husband during labour: OR [95% CI], 2.5 [1.19-5.24]; p=0.014) [Table 3].

Discussion

A mother's intention to breastfeed is the single most important factor in deciding whether she will start breastfeeding and how long she will continue. In this study, the initiation of skin-to-skin contact in the labour ward was found to have a statistically significant correlation with maternal intention to breastfeed and sustained breastfeeding at 4 weeks post-delivery.

Skin-to-skin contact is a natural process that places a naked newborn chest down on the mother's bare chest immediately or shortly after birth. It is also recognised to have enormous and lasting emotional and physical benefits for mother and baby. During the process, both mother and baby will be calm and relaxed. The baby's temperature and breathing rate will be more stable and normal, and the blood sugar is more elevated as warmth is provided by the mother.

From the point of view of breastfeeding, if the baby is kept in skin-to-skin contact with the mother for at least an hour, it is more likely to latch on well. When the mother touches her baby, the sensation will encourage the baby to crawl, seek out and grasp its mother's nipple, then open its mouth and lick the nipple. This attachment will stimulate the release of essential hormones to support breastfeeding, such as oxytocin and prolactin, that will facilitate milk flow and enhance milk production respectively[9]. There are now a multitude of studies to show that mothers would breastfeed for a longer duration if they had experienced skin-to-skin contact soon after delivery[10-12].

It is suggested that skin-to-skin contact should last

for at least an hour or until the end of the first breastfeed. Nonetheless, in this study we did not analyse whether the maternal intention or sustainability of breastfeeding was affected by the duration of skin-to-skin contact. Besides, the data only compared mothers with and without any skin-to-skin contact with their babies after delivery.

Second, maternal intention to breastfeed and sustained breastfeeding at 4 weeks post-delivery were also found to have statistically significant correlation with the presence of the husband during labour. Fathers are often the most influential support prior to birth in feeding decisions and throughout the breastfeeding period[13,14]. In addition, fathers play a vital role as supporter of breastfeeding especially when they have a positive attitude towards its continuation[14,15]. In Şencan et al's study[16], the duration of breastfeeding was correlated with the father's engagement in the labour process and breastfeeding. Thus, it is more likely that the mother will elect to breastfeed if she receives a principally positive, or at least neutral reaction from her significant others[8].

Conclusion

This study suggested that skin-to-skin contact and presence of the husband during labour should be promoted and advocated. These factors are important for us to develop promotional policies and provide effective counselling in order to improve the breastfeeding rate and sustain a longer duration of breastfeeding.

Declaration

All authors have disclosed no conflicts of interest.

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Combined Preimplantation Genetic Diagnosis for a Monogenic Disease and Aneuploidy Screening with Array Comparative Genomic Hybridisation — First Live Birth in Hong Kong and a Review of the Approach

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Preimplantation genetic diagnosis (PGD) is an alternative of reproductive options of couple with genetic diseases. Alpha-thalassaemia is one of the most common indications for PGD in our locality. In the past, only target gene location could be detected during PGD treatment. However, after the recent advances in the technique of whole-genome amplification, the addition of aneuploidy screening in the PGD treatment cycles may provide further advantage. It can avoid aneuploidy or other chromosomal abnormalities of the newborn after PGD. We reported our first live birth in Hong Kong after this combination approach. It illustrated that it can be an attractive option for couples with genetic diseases or predisposition to genetic diseases.
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Keywords: Aneuploidy; Genomics/methods; Genetic diseases, inborn; Genetic testing/methods; Preimplantation diagnosis

Case Report

A 33-year-old woman was referred to the reproductive genetic counselling clinic of Queen Mary Hospital in December 2012 with a request for preimplantation genetic diagnosis (PGD) for alpha-thalassaemia. She had previously had three spontaneous pregnancies, one ending in early miscarriage and the other two complicated by haemoglobin Bart's hydrops fetus with consequent termination in the second trimester. The couple were found to carry the heterozygous --Southeast Asian (SEA) deletion in alpha-globin genes. After genetic counselling, the couple was very keen to undergo PGD for alpha-thalassaemia in order to avoid further pregnancies with haemoglobin Bart's hydrops. They also raised their concern about trisomy pregnancies and requested aneuploidy screening in the same setting of PGD. After extensive counselling, combined PGD for alpha-thalassemia and aneuploidy screening was offered.

The patient underwent one in-vitro fertilisation treatment cycle in April 2013 in an agonist protocol. Forty-four oocytes were retrieved and 42 were mature for intracytoplasmic sperm injection; of which 35 were normally fertilised and 16 good-quality embryos were available for blastomere biopsy on day 3. Whole-genome amplification (WGA) was performed on a single blastomere[1]. After gap polymerase chain reaction for the alpha-globin gene and microsatellite markers flanking alpha-globin gene loci, 12 embryos were determined to be either normal or a carrier of the alpha-thalassaemia --SEA deletion. Aneuploidy screening was performed on the same WGA product with array comparative genomic hybridisation (aCGH) according to the manufacturer's protocol (24sure V3; Illumina, Cambridge, United Kingdom). No aneuploidy was detected in nine embryos, but seven embryos had various chromosomal abnormalities, including trisomies 4 and 18, monosomy 22, and segmental aberrations (Figure 1). In summary, of the 12 embryos that were either normal or a carrier of alpha-thalassaemia, only seven had no aneuploidy detected on aCGH (Figure 2). These seven

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blastocysts were of good quality and vitrified on day 5. The patient underwent frozen-thawed blastocyst transfer in September 2013 with one blastocyst transferred resulting in a singleton pregnancy. She delivered a full-term baby boy weighing 3.17 kg by Caesarean section on 9 June 2014.

Discussion

Since the development of PGD, more than 10,000 treatment cycles have been performed worldwide[2]. We developed our PGD service in 2001 and the first birth after PGD was in 2002. As thalassaemia is prevalent in our locality, it was the first monogenic disease to be targeted by our PGD service. For alpha-thalassaemia, an autosomal recessive disease, the most common type of alpha-globin gene mutation is deletion of two alpha-globin genes, the --SEA deletion. The most common cause of haemoglobinopathy hydrops in South-East Asians is being homozygous for the --SEA mutation, i.e. no alpha-globin gene present. These fetuses will exhibit abnormal ultrasound features in early pregnancy including cardiomegaly and placentomegaly, making early diagnosis possible. As this abnormality is not compatible with life, the couple will generally elect to abort the fetus. For couples with heterozygous --SEA deletions, 25% of their offspring can be expected to suffer from haemoglobin Bart's disease.

Our patient had two consecutive pregnancies affected by the disease. Because of the possibility of psychological trauma related to the previous abortions, she was very reluctant to accept the risk of an aneuploidy pregnancy that could result in a miscarriage or another abortion. Although the risk of aneuploidy, especially trisomy 21, in human pregnancies rises after maternal age above 35 years, 70% of children with Down syndrome are born to women below 35 years. Morphological assessment of blastocysts under the microscope alone cannot distinguish aneuploid blastocysts from euploid ones. Transfer of aneuploidy blastocysts most likely ends up as either implantation failure, miscarriage, or delivery of a congenitally abnormal baby[3]. A strategy of screening for aneuplodies can thus potentially shorten the time to successful delivery of healthy babies.

With the development of WGA and comprehensive chromosomal screening (CCS), combined PGD for monogenic diseases and aneuploidy screening is possible with one biopsy. We have previously demonstrated the feasibility of simultaneous PGD for alpha-thalassemia and aCGH on the same biopsy sample[1]. In this cohort of embryos, five (41.7%) genetically replaceable embryos on alpha-globin locus were found to be abnormal after aneuploidy screening. The benefits of using preimplantation genetic screening (PGS) with PGD include a significant reduction in pregnancies with chromosomal abnormalities and a possible reduction in miscarriages. Nonetheless, this strategy requires a good number of embryos for selection and may only benefit women with good ovarian reserve.

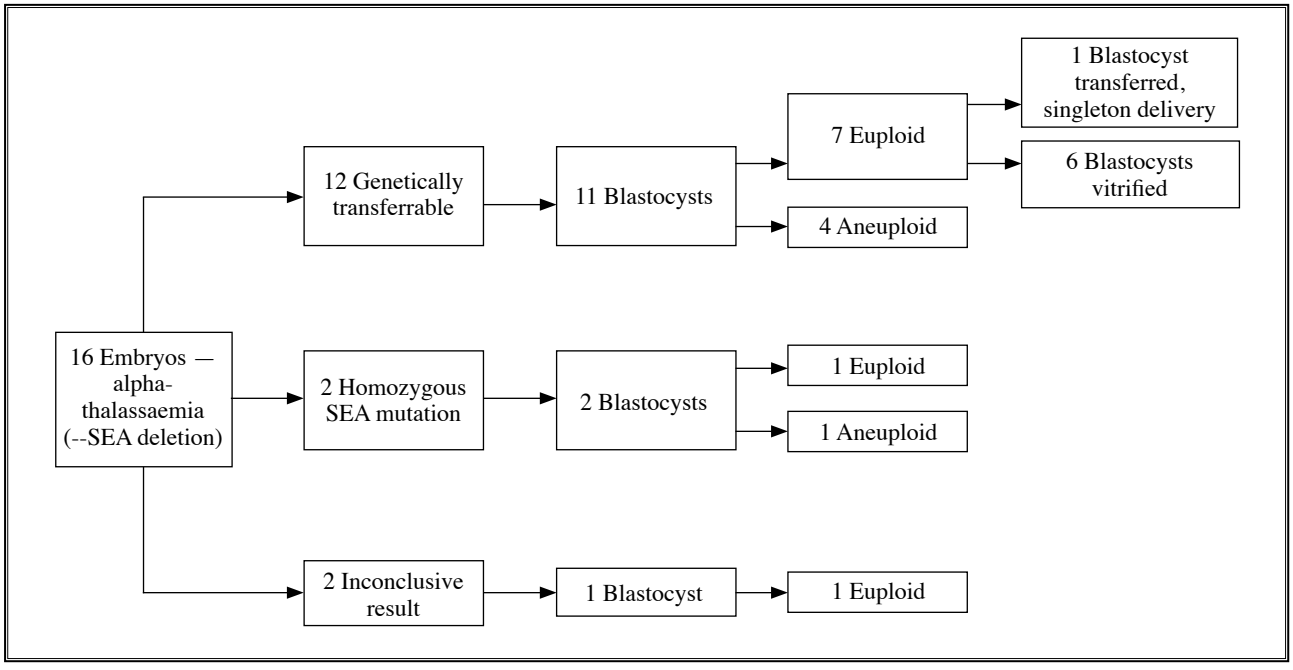


Figure 1. Results of preimplantation genetic diagnosis and aneuploidy screening

Abbreviation: SEA = Southeast Asian

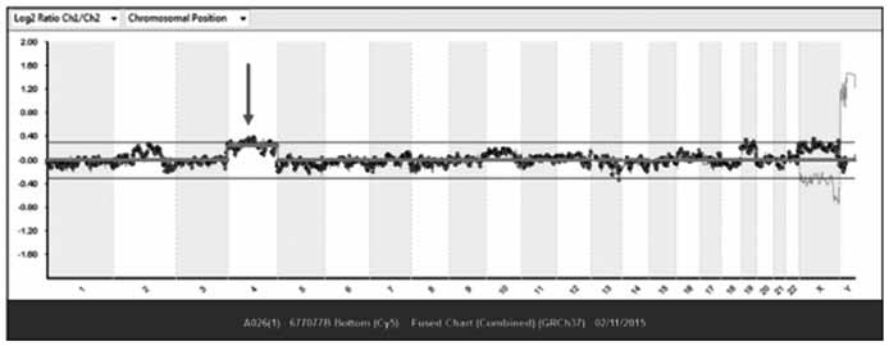
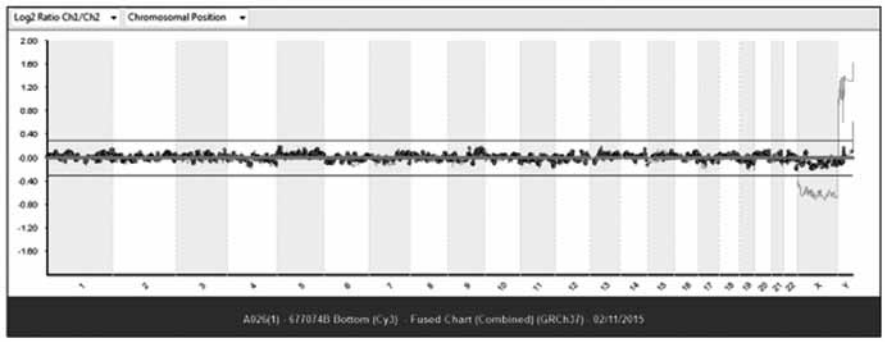
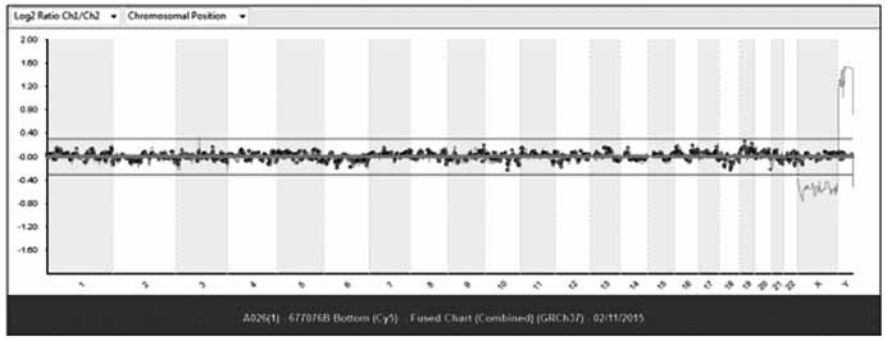
Embryo (quality on day 5)	Genotype	PGS result
7 (5BB)	Normal or alpha-thalassemia-1	Trisomy 4 
19 (5CB)	Homozygous for alpha --SEA deletion	No aneuploidy detected 
42 (5AA)	Normal	No aneuploidy detected 

Figure 2. Examples of preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) result on good-quality blastocysts

Genetically replaceable but aneuploidy (embryo 7); the arrow depicted the gain in chromosome 4. Genetically non-replaceable but no aneuploidy detected (embryo 19). Genetically replaceable and no aneuploidy detected (embryo 42). The embryos have been replaced in frozen-thawed cycle and result in normal live birth of a baby boy

We offer this strategy to all couples undergoing PGD for monogenic diseases, and detailed counselling is provided to them before making a decision.

The use of PGS with CCS in assisted reproductive technology treatment cycles has been a topic hotly debated in the last couple of years. The potential advantages of this strategy include improved efficacy, shortened interval to live birth, reduced miscarriage rate and implantation failure. Nonetheless, there is debate about the potential problems arising from this use, similar to the enthusiasm about using PGS with fluorescent in-situ hybridisation (FISH) about two decades ago. Subsequently, a meta-analysis of 11 randomised trials demonstrated that this approach of using PGS with FISH did not improve the pregnancy rate at all[4]. The problems of using FISH lie in

the fact that only five chromosomes can be tested in one round and repeated rounds to test more chromosomes can hamper diagnosis accuracy. In addition, aneuploidies can arise from all chromosomes[5], and could explain partially the reason why PGS using FISH failed to improve the success rate. Also, in early cleavage embryos, mosaicism is very common as 70% of good-quality embryos are mosaic in nature. The percentage of mosaicism in blastocysts would be lower than in cleavage stage embryos, so using the trophectoderm biopsy with CCS in PGS can hopefully achieve the potential benefits. Nonetheless, before we fall into the same trap similar to 20 years ago[6], large randomised trials are urgently needed prior to the routine use of PGS with CCS in artificial reproductive technology settings.

Our case showed a potential but clear benefit of combining PGS with CCS in couples undergoing PGD for monogenic diseases. Careful patient counselling is vital. The combined screening approach should not be the routine treatment for couples undergoing PGD for monogenic diseases.

Declaration

All authors have disclosed no conflicts of interest.

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Non-invasive Prenatal Test as Primary Screening for Down Syndrome

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The performance of non-invasive prenatal testing (NIPT) is superior to that of current Down screening methods in both high- and low-risk pregnancies. On the other hand, concern over loss of benefits from current screening strategy for Down syndrome after its replacement by NIPT is not substantiated. The ethical principles of equity and reproductive autonomy also favour NIPT for universal screening. A preliminary analysis showed that the current Down screening strategies in the Hospital Authority could be replaced by NIPT without increasing the expense per case of trisomy 21 diagnosed from a societal perspective. In fact, the use of NIPT as a primary screening test for all pregnant women has been endorsed by the International Society of Prenatal Diagnosis.
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Keywords: Down syndrome; Prenatal diagnosis

Introduction

Non-invasive prenatal testing (NIPT) can be used as a first-tier screening test or a second-tier test for cases screened positive using conventional screening methods. There are three main concerns using NIPT as a universal first-tier test: (1) the test performance in a low- or mixed-risk obstetric population; (2) potential loss of other benefits offered by the current Down screening programme; and (3) the relatively high cost of NIPT.

Test Performance in the General Obstetric Population

NIPT has an excellent performance in a routine obstetric population. Since the first study in low-risk women in 2012, there have been at least 13 large studies, each with more than 1000 women, on the performance of NIPT for Down syndrome screening in a low-risk obstetric population[1-13]. The total number of women studied exceeds 123,000. All studies showed that the rate of indeterminate results is extremely low (1.2-4.8% on first sample and 0.0-1.9% after redraw). The detection rate is >99.9%, comparable with that in the high-risk group. The false-positive rate was ≤0.3%, comparable with that in the high-risk group, and much lower than that of current screening strategies (false-positive rate, 4%)[1-13]. The positive predictive value ranges from 46% to 91%, again many fold higher than that of current methods (positive predictive value, 4.2%)[1-13]. It is no longer justifiable to offer pregnant women a test that has a poor positive predictive value and a high false-positive rate[14].

Loss of Other Benefits of Current Down Screening Programme

The current Down screening programme sometimes detects other unrelated chromosomal abnormalities. Some are worried that these may be missed by targeted NIPT. Nonetheless, these conditions do not fulfil the criteria for screening. Many of them are randomly distributed and are not more common with a positive Down screening result. They are picked up simply due to the higher false-positive rate of the current Down screening programme and therefore more invasive diagnostic procedures are performed. It is the downside, and not an additional benefit, of current Down screening methods.

Atypical autosomal aneuploidies are rare after 12 weeks because they are lethal beyond the first trimester. Why bother then? The phenotypes of sex chromosome abnormalities and other autosomal aberrations are variable, usually mild. Findings of unclear significance sometimes arise secondary to a false-positive Down screening result. These conditions cause complex counselling issues, especially in the absence of ultrasound abnormalities. They unnecessarily overload the highly sought genetic counselling service. There are significant ethical issues as well. Adequate pretest counselling is impossible given the

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multitude of possibilities associated with a false-positive Down screening result. It poses potential psychological harm to the woman due to unpreparedness, anxiety, and shock. Knowing more is not necessarily a blessing. To avoid this pitfall, the UK National Screening Committee has wisely recommended quantitative fluorescent polymerase chain reaction confirmation of a positive Down screening result[15].

Coupled with maternal characteristics, blood pressure, and uterine artery Doppler, the current Down screening programme has the potential to predict development of pre-eclampsia and small babies. Nonetheless, the need for multiple markers means individual markers are not good enough. Replacing the current programme with NIPT, only the biochemical markers are lost. This is acceptable since biochemistry is not a good marker.

Ultimately, nothing is missed switching to targeted NIPT and it helps to alleviate the problems caused by the much higher false-positive rate of current screening methods. Nonetheless, NIPT is not a substitute for quality prenatal ultrasound, instead the two are complementary.

Cost

Two recent studies from the US examined the cost of replacing current screening strategies with NIPT from a societal perspective, i.e. taking into consideration the lifetime cost of the birth of an affected child. In one[16], if NIPT cost was ≤US$744, conventional Down screening strategies could be replaced by NIPT without increasing the total health care expenditure. NIPT in this analysis reported trisomies 13 and 18 and Turners syndrome, as well as trisomy 21. Another study[17] showed that if NIPT cost was ≤US$665, first trimester screening (FTS) could be replaced by NIPT without increasing the societal cost per trisomy case diagnosed. If NIPT cost was ≤US$543, then FTS could be replaced without an increase in total cost. In this study, NIPT reported trisomies 13 and 18 as well as trisomy 21. To date, no cost-effective analysis can address the psychological and non-monetary benefits of NIPT.

A preliminary analysis was carried out to assess the differential performance and cost-effectiveness of replacing the current Down screening strategy in the Hospital Authority with NIPT. The unit NIPT cost per case of trisomy 21 diagnosed was reported to be no higher than that of the current Down screening programme. The cost from a societal perspective is calculated by taking into account the lifetime cost of the birth of an affected child, and includes the difference in direct medical and educational costs between a Down syndrome child and an average individual in addition to the indirect costs of lost productivity due to morbidity and mortality associated with Downs. NIPT outperforms the current screening strategy (Table 1[18,19]). When NIPT charge was US$160-300 (a range reported taking into account the variation in lifetime cost estimate of an affected child), the expense per case of trisomy 21 diagnosed was not increased (Table 2[16,18,20]).

The market price of NIPT has already reduced to US$300 and was lower in 2014[21,22]. It was recognised that, in Hong Kong, the test could be offered at <HK$2000 (US$250) with the provider already making a good profit. These providers and their intermediates (such as private doctors and hospitals) are making a huge profit by offering the test at HK$8000[23]. One major NIPT provider from China has conceded that profit was made by offering NIPT at around US$160 (personal communication). Therefore, replacing current screening strategies with NIPT at no additional cost is economically feasible.

Further fall in NIPT cost is expected for good reasons. The principal reason is advances in technology. Chromosome-selective sequencing, semiconductor sequencing, and microarray-based analysis all have good potential to reduce costs compared with massively parallel sequencing. Revolutionary third-generation sequencing, or nano-sequencing will soon be available. The second reason is the economics of scale attributed to increasing uptake of NIPT. The third reason is price negotiation with government participation, through incentive structure, regulations, and reimbursement policies. The fourth is competition. Today, there are at least 13 NIPT providers worldwide. Three more are forthcoming in the US. The competition is keen. Almost all NIPT providers in the US are embattled in lawsuits over enforcement and infringement of patents. In a recent case, the court invalidated the "540 patent" and denied Sequenom's request for an injunction against Ariosa Diagnostics (San Jose, California)[24]. Nonetheless, even if not invalidated, the "540 patent" will expire by 2017, paving the way for further reductions in NIPT cost.

Ethical Considerations

From an ethical point of view, there are also strong grounds for NIPT for all (equity of access) and not just for a select few. If NIPT is an important and beneficial technology, it should be available to all patients[25]. When NIPT is used as a second-tier test, the risk cut-offs to define high-risk groups eligible for NIPT differ widely in different studies. The eligibility for NIPT as a secondary test is

Table 1. Clinical performance of non-invasive prenatal test as first-tier test versus that of current screening strategy in the Hospital Authority (assuming 50,000 deliveries/year)

Clinical performance	First-tier non-invasive prenatal test	Current screening
Detection rate[18]	99%	93%
False-positive rate[18]	0.3%	5%
No. of trisomy 21 fetus/year[19]	117	117
Screening positive	116	109
No. of invasive tests*	266	2603
Procedure-related loss[19]	2	23

* No. of invasive tests = ([Total No. of annual deliveries (assumed 50,000) – No. of trisomy 21 fetus/year] x false-positive rate) + No. of screen-positive cases

Table 2. Cost analysis

Item	Unit cost (HK$)
Serum assay[18]	220
Invasive procedure[18]	1900
Polymerase chain reaction*	900
Karyotyping*	1600
Human capital†	54,350
Ultrasound machine‡	0.8 million
Lifetime cost of affected child[16,20]	5.3-11.7 million
Non-invasive prenatal test cost to keep expense per case of trisomy 21 diagnosed constant from a societal perspective§	1250-2340 (US$160-300)

* Data from Tsan Yuk Hospital Prenatal Diagnosis Laboratory

† Mean monthly salary of specialist midwife responsible for nuchal translucency scanning and pretest counselling (salary quoted from Hospital Authority vacancy for advanced practice nurse)

‡ Philips IU22 ultrasound machine

§ First-trimester ultrasound for nuchal translucency is retained after implementing universal non-invasive prenatal test

subject to manipulation. This has raised significant ethical concerns.

In a civilised society, free choice is highly valued. If the government is unable to or hesitates to offer the benefit of NIPT for all, a publically funded coupon will be a much better choice than a centralised service offering an inferior/less optimal test[23].

Acceptance of Universal Non-invasive Prenatal Test

We are not alone in the pursuit for NIPT for all. In a recent survey of members of the American College of Obstetricians and Gynecologists (ACOG), the majority (79.1%) were of the view that NIPT should be offered to all patients, similar to current Down syndrome serum and ultrasound screening[26]. In the Netherlands, replacement of FTS by NIPT is favoured by 72% of health care professionals. The majority found NIPT easier to explain to patients than conventional screening[27].

Endorsement by Major Professional Bodies

In 2015, the ACOG and International Society of Prenatal Diagnosis (ISPD) revised their guidelines to keep up with the rapid developments in the field. The ACOG, in conjunction with the Society for Maternal-Fetal Medicine in the US, stated that any patient may choose NIPT as a screening strategy for common aneuploidies regardless of her risk status[28]. In 2015, the ISPD also considered it appropriate to offer NIPT as a primary test to all pregnant women[29]. The European Society of Human Genetics and American Society of Human Genetics also released their joint statement in 2015 in support of universal NIPT[30].

Conclusion

NIPT has superior efficacy to conventional screening for all pregnant women. The replacement of the current Down screening strategy with universal NIPT can potentially be achieved without adding to the overall cost from a societal perspective. The next question will be how to maximise its benefits to pregnant women in the local setting.

Declaration

The author has disclosed no conflicts of interest.

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An Update on the Management of Endometrial Hyperplasia

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Endometrial hyperplasia is known to be a precursor lesion for development of endometrial adenocarcinoma, which is the most common gynaecological cancer in Hong Kong. Recently, the Royal College of Obstetricians and Gynaecologists/British Society for Gynaecological Endoscopy (RCOG/BSGE) published a joint guideline in February 2016 on the management of endometrial hyperplasia. In this article, we review the development of the classification of endometrial hyperplasia, as well as the investigation and management of endometrial hyperplasia in reference both to the Hong Kong College of Obstetricians and Gynaecologists and RCOG/BSGE guidelines.
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Keywords: Endometrial hyperplasia; Guidelines as topic

Introduction

Endometrial cancer is the most common gynaecological malignancy in Caucasians and locally in Hong Kong. It ranks fourth among the most common cancers in Hong Kong females[1]. Endometrial hyperplasia is known to be a precursor lesion for endometrial adenocarcinoma. It is defined as irregular proliferation of the endometrial glands with an increase in the gland-to-stroma ratio when compared with proliferative endometrium[2].

In this article, we review the investigation and management of endometrial hyperplasia with reference to the recent Hong Kong College of Obstetricians and Gynaecologists (HKCOG) guidelines[3] published in September 2015 and the Royal College of Obstetricians and Gynaecologists/British Society for Gynaecological Endoscopy (RCOG/BSGE) joint guideline[4] published in February 2016.

Classification

Previously, the most widely adopted classification for endometrial hyperplasia was the World Health Organization (WHO) 1994 classification system[5], in which endometrial hyperplasia was classified into four categories based on the glandular architectural complexity and nuclear atypia: (i) simple hyperplasia, with 1% risk of progression to endometrial cancer; (ii) complex hyperplasia, with 3% risk of progression to endometrial cancer; (iii) simple hyperplasia with atypia; and (iv) complex hyperplasia with atypia. The last two have a higher risk of progression to endometrial cancer of 8% and 29%, respectively[6]. Among complex hyperplasia with atypia, a 50% risk of concomitant cancer has been reported[7].

In 2000, the Endometrial Collaborative Group redefined the terminology. Endometrial precancers were collectively designated endometrial intraepithelial neoplasia (EIN) in recognition of their monoclonal growth. This also avoids confusion with a benign hormonal effect[8]. Long-term follow-up study of women with endometrial hyperplasia suggested that the EIN classification has higher accuracy to predict the development of future malignancies than the WHO 1994 classification[9], but the system is not extensively used in the UK or locally in Hong Kong.

The WHO 2003 classification defines EIN as a 'histological presentation of premalignant endometrial disease as identified by integrated molecular genetic, histomorphometric and clinical outcome data', with only 79% of atypical hyperplasia translating to EIN[7]. In the latest WHO classification published in 2014, endometrial hyperplasia is simply divided into two categories: (i) hyperplasia without atypia and (ii) atypical hyperplasia. Atypical hyperplasia exhibits mutations that are typical of invasive endometrial cancer, and these changes are not evident in hyperplasia without atypia. The 2014

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classification system not only allows interchangeable diagnosis between EIN and atypical hyperplasia, it also reflects a new understanding of molecular genetic changes[10].

Methods of Diagnosis

Histological examination of endometrial tissue is necessary to diagnose endometrial hyperplasia. Outpatient endometrial sampling is convenient and has a high overall accuracy for diagnosing endometrial cancer. The RCOG/BSGE guidelines[4] suggest diagnostic hysteroscopy when outpatient endometrial sampling fails or is non-diagnostic, or when endometrial hyperplasia is diagnosed within a polyp or other discrete focal lesion. The HKCOG guidelines[3] suggest diagnostic hysteroscopy with targeted biopsy or dilatation and curettage, when endometrial hyperplasia is diagnosed on endometrial biopsy, in order to exclude carcinoma or atypical endometrial hyperplasia before commencement of treatment.

In a meta-analysis of accuracy of endometrial sampling, the sensitivity for detecting cancer in postmenopausal and premenopausal women using pipelle was 99.6% and 91%, respectively. For atypical hyperplasia, the sensitivity was 81%[11]. The diagnostic accuracy of hysteroscopy alone for hyperplasia is only modest when compared with that of cancer[12], therefore targeted biopsy or dilatation and curettage should be performed with diagnostic hysteroscopy to improve the diagnostic accuracy.

With regard to imaging, transvaginal ultrasound may play a role in diagnosis. It helps to detect any endometrial polyp or focal lesion by assessing the regularity of the endometrial lining. For diagnosis of endometrial hyperplasia, it should be performed in conjunction with endometrial biopsy for histological examination. Computed tomographic scan and magnetic resonance imaging (MRI) are not routinely recommended.

Treatment and Surveillance

An algorithm for the management of endometrial hyperplasia is illustrated in the Figure.

Endometrial Hyperplasia without Atypia

The cumulative 20-year progression risk among women with endometrial hyperplasia without atypia is less than 5%. Most cases will regress[13]. Women should be informed that treatment with progestogen has a higher regression rate than observation alone. The regression rate ranges from 74.2% to 81%[6,14] for observation alone compared with 89% to 96% for progestogen treatment[15]. Importantly, reversible risk factors, such as obesity and hormone replacement therapy (HRT), should be identified and corrected if possible.

The first-line progestogen treatment is insertion of a levonorgestrel-releasing intrauterine system (LNG-IUS) that can achieve a higher local concentration and higher regression rate, with less systemic side-effects. Patients are also less likely to require hysterectomy[16]. In addition, LNG-IUS provides effective contraception. The minimal treatment duration is 6 months for regression of disease, although in women with endometrial hyperplasia without atypia up to 5 years is preferable provided any adverse effects are tolerable[4].

An alternative for women who decline LNG-IUS is oral continuous progestogens. The suggested effective regimens include medroxyprogesterone 10 to 20 mg/day, norethisterone 10 to 15 mg/day, and megestrol 160 to 320 mg/day[3]. Similarly, the minimal treatment duration is 6 months. If endometrial hyperplasia persists despite 6 months of treatment with oral continuous progestogens, LNG-IUS should be offered. Cyclical progestogens have been shown to be less effective in inducing regression of endometrial hyperplasia compared with the continuous regimen[17]. Observation or other treatments such as endometrial ablation, combined pills, and gonadotrophin-releasing hormone agonists are not routinely recommended. In view of the high regression rate with progestogen, hysterectomy is not offered as the first-line treatment. It is only indicated in those who show no regression after 12 months of treatment, who progress to atypical hyperplasia, relapse after treatment completion, or have persistent abnormal bleeding, and those who decline to comply with treatment and surveillance.

According to the RCOG/BSGE guidelines[4], endometrial surveillance for endometrial hyperplasia without atypia should be performed every 6 months. In low-risk women, at least two consecutive negative endometrial biopsies are needed prior to discharge. In women at higher risk of relapse such as those with body mass index of ≥ 35 kg/m^2 or those who are treated with oral progestogens, long-term follow-up with annual endometrial sampling is required after two consecutive negative endometrial biopsies. The HKCOG guidelines[3] recommend endometrial sampling every 6 months for 2 years after completion of treatment. Women can be discharged if regression is achieved. Women should be advised about the risks of late recurrence and to seek medical attention if abnormal bleeding occurs.

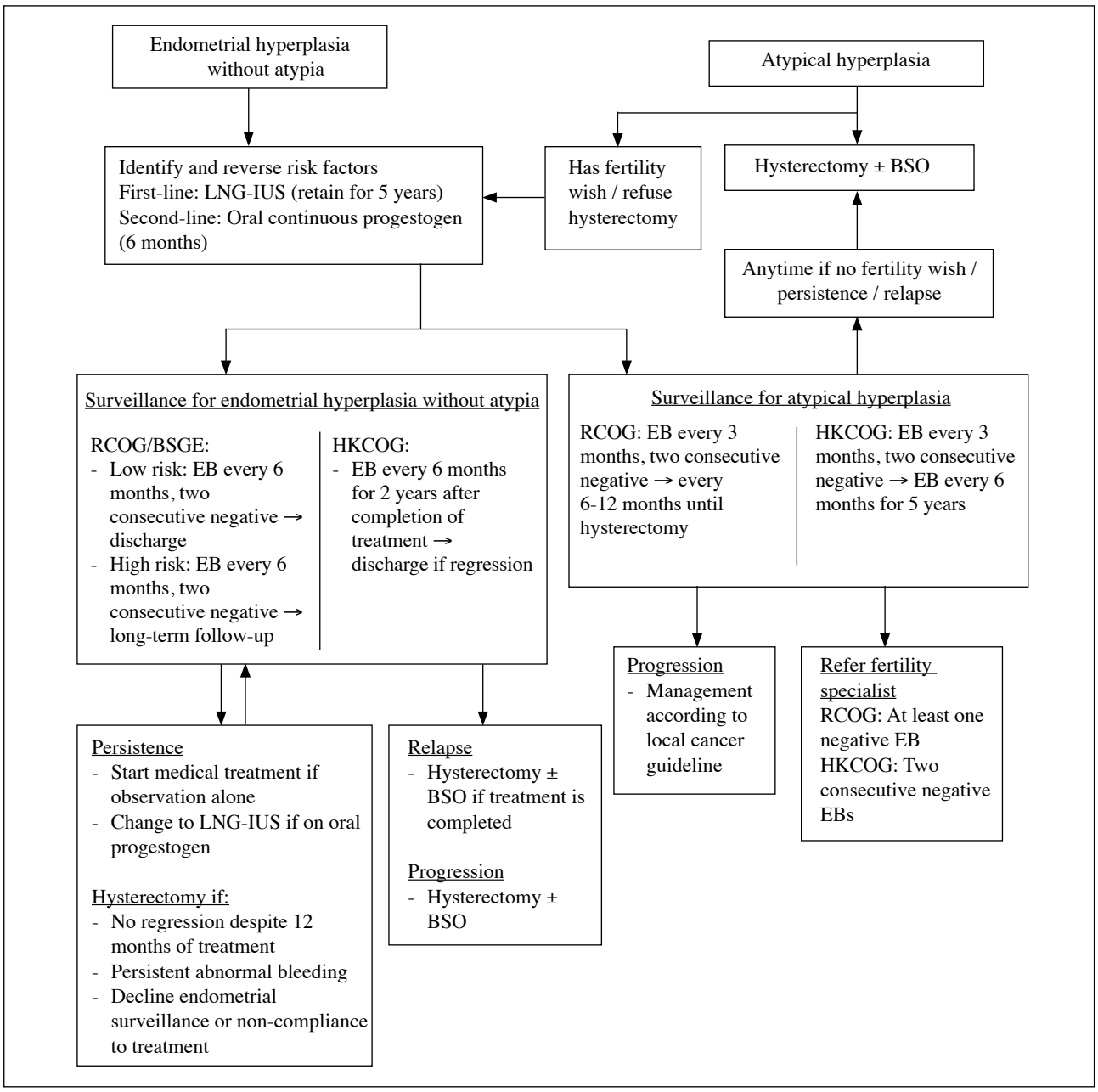

Figure. Algorithm for the management of endometrial hyperplasia

Abbreviations: BSO = bilateral salpingo-oophorectomy; EB = endometrial biopsy; HKCOG = Hong Kong College of Obstetricians and Gynaecologists; LNG-IUS = levonorgestrel-releasing intrauterine system; RCOG/BSGE = Royal College of Obstetricians and Gynaecologists//British Society for Gynaecological Endoscopy

Atypical Hyperplasia

The risk of progression to malignancy is 30% with a risk of concomitant cancer (40-50%) for atypical hyperplasia[6,7]. Thus, total hysterectomy is offered as the first-line treatment. If hysterectomy is to be performed in postmenopausal women, total hysterectomy with bilateral salpingo-oophorectomy is recommended, whereas for premenopausal women, total hysterectomy with bilateral salpingectomy is recommended. The decision to perform bilateral salpingo-oophorectomy should be taken on an individual basis.

Women who wish to retain their fertility or refuse hysterectomy should be counselled about the risks of concomitant endometrial cancer and progression to endometrial cancer, the importance of endometrial surveillance and to delay conception until disease regression. The first-line fertility-sparing treatment is LNG-IUS, and the second-line treatment is oral continuous progestogens. Underlying endometrial cancer should be excluded by hysteroscopy with targeted biopsy or dilatation and curettage. Investigations such as transvaginal ultrasound scan help to exclude ovarian lesions. Tumour

markers (such as CA125) and MRI scan can be considered if clinically indicated.

According to the RCOG/BSGE guidelines[4], endometrial surveillance for women undergoing fertility-sparing treatment should be performed every 3 months. Hysteroscopy with targeted biopsy or dilatation and curettage can be considered as the endometrial sampling method. After two consecutive negative endometrial biopsies, endometrial surveillance every 6 to 12 months should be arranged until hysterectomy is performed. Endometrial sampling can be considered in low-risk women without persistent abnormal uterine bleeding. The HKCOG guidelines[3] advocate endometrial surveillance every 3 months. After two consecutive negative endometrial biopsies, endometrial surveillance can be performed every 6 months for 5 years.

Women who wish to conceive can be referred to a fertility specialist after at least one negative endometrial sample according to the RCOG guidelines, or after two consecutive negative endometrial biopsies according to the HKCOG guidelines[3]. The rationale is that regression of disease is associated with higher implantation and clinical pregnancy rates.

Endometrial Hyperplasia in Special Groups of Women

Women on Hormone Replacement Therapy

It is generally agreed that oestrogen-only HRT should not be used in women with an intact uterus. The indication for HRT should be reviewed carefully. Women with endometrial hyperplasia who wish to continue HRT should be advised to have continuous progestogen, such as LNG-IUS or a continuous combined HRT preparation.

Women on Tamoxifen

Women should be informed about the risks of endometrial hyperplasia and cancer with the use of tamoxifen, but not those taking aromatase inhibitors (e.g. anastrozole, exemestane, and letrozole). Although there is evidence that prophylactic insertion of LNG-IUS can decrease both the formation of endometrial polyps and endometrial hyperplasia[18], its routine use cannot be recommended because of the uncertain risk of breast cancer recurrence.

Women with a History of Hyperplasia Managed according to the Old Classification System

Under the old 1994 WHO classification of endometrial hyperplasia[5], among women with simple hyperplasia without atypia who had a very low risk of disease progression (1%), some were prescribed routine treatment according to their menstrual symptoms. With reference to the new classification system and updated guidelines, treatment with progestogens and endometrial surveillance is required for this group of women. They should be well informed and counselled about the recent evidence and treatment recommendations.

Conclusion

Endometrial hyperplasia is a precancerous lesion that is not uncommon. We should be updated in the classification system and the recommendations in management. The diagnosis can be confirmed by endometrial sampling, or more accurately, by hysteroscopy with targeted biopsy or dilatation and curettage. The first-line treatment of hyperplasia without atypia is insertion of LNG-IUS, and that of atypical hyperplasia is hysterectomy with or without bilateral salpingo-oophorectomy if no fertility wish. In special cases such as those with atypical hyperplasia with fertility wish and those with progression to malignancy, referral to subspecialist care is suggested.

Declaration

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Promote, Protect, and Support Breastfeeding: What is the Role of Obstetricians?

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The World Health Organization recommends exclusive breastfeeding for the first 6 months of an infant's life. In Hong Kong, although many mothers initiate breastfeeding, most do not continue as long as they had planned. Common reasons for discontinuation were insufficient breast milk, tiredness and fatigue, return to work, lack of support, and introduction of formula feeding before 1 month. The American College of Obstetricians and Gynaecologists strongly supports breastfeeding and calls on its Fellows, other related professionals, hospitals, and employers to support women in choosing to breastfeed their infants. Obstetricians, in collaboration with paediatricians, lactation consultants and other disciplines can help promote, protect, and support breastfeeding in the antepartum, intrapartum, and postpartum period. They can also support policy efforts in hospitals and workplaces that enable women to breastfeed. All obstetricians should improve their knowledge about breastfeeding to benefit babies and mothers.
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Keywords: Breast feeding; Obstetrics; Postpartum period

Introduction

The World Health Organization (WHO) recommends exclusive breastfeeding for the first 6 months of an infant's life. The benefits of breastfeeding to the baby and their mother are well documented and include protection from infection, biological signals to promote cellular growth and differentiation, reduced maternal postpartum blood loss, and reduced risk of ovarian and breast cancer[1-6]. Breastfeeding is also good for society and the environment. This article will discuss the reasons for low exclusive breastfeeding rates at 4 to 6 months, and how obstetricians can help promote, protect, and support breastfeeding.

Discontinuation of Breastfeeding

In Hong Kong, the breastfeeding rate on hospital discharge increased from 19.0% in 2002 to 86.3% in 2015[7]. Nonetheless, the exclusive breastfeeding rate for babies up to 4 to 6 months old was only 27%[7]. In other words, although many mothers initiated breastfeeding, most did not continue. Common reasons for discontinuation were insufficient breast milk, tiredness and fatigue, return to work, lack of support, and introduction of formula feeding before 1 month[7,8]. If mothers experience breastfeeding problems and health care providers are ill-equipped to manage these problems and instead advise mothers to supplement with formula, then mothers are more likely to discontinue exclusive breastfeeding[9]. Previously, residents and obstetrician-gynaecologists have been found to be ill-informed about the benefits of breastfeeding and clinical management[10]. Training in infant nutrition was lacking or inadequate[11].

Support Breastfeeding

Support from health care providers in the hospital, from family members at home, from employers in the workplace, and from the community can increase a mother's confidence and experience in breastfeeding[12-16]. The American College of Obstetricians and Gynaecologists (ACOG) strongly supports breastfeeding and calls on its Fellows, other related professionals, hospitals, and employers to support women in choosing to breastfeed their infants[13]. Obstetricians are in an ideal position to assist women to make an informed decision about feeding, offer anticipatory guidance, support normal lactation, and manage breastfeeding problems[17]. It is preferable to integrate care by the obstetrician, paediatric provider, and lactation consultant and involve family members[17,18]. On the contrary, an opinion leader strategy (i.e. an expert to influence the behaviour of health care professionals) should

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be discouraged as it does not improve breastfeeding rates[19].

Training

Obstetricians should be adequately trained and continuously educated if they are to provide accurate information about breastfeeding to expectant mothers and be prepared to support them should any breastfeeding problems arise. The ACOG recommends that all obstetrician-gynaecologists and other obstetric care providers should develop and maintain knowledge and skills in anticipatory guidance, physical assessment and support for normal breastfeeding, and management of common lactation problems[20]. The Department of Health has prepared an educational CD on breastfeeding for health care workers. The Obstetric and Gynaecological Society of Hong Kong has devised questions based on the CD. Fellows are able to complete the test and earn continuous medical education points that are accredited by the Hong Kong College of Obstetricians and Gynaecologists. In addition to knowledge and practical skills, obstetrician attitude to their responsibility for and the benefits of infant feeding counselling are equally important[19].

Antepartum

The ACOG recommends obtaining a breastfeeding history, identifying concerns and risk factors for breastfeeding difficulties, and communicating these to the infant's health care provider[20]. Physical examination of the breasts can identify congenital anomalies, inverted nipples or prior breast surgery, all of which can hinder lactation[21]. Mothers should be counselled about the benefits of breastfeeding, starting as early as the first trimester[18]. Those who are unable to obtain quality health care for socio-economic reasons are more likely to face greater barriers to initiation and continuation of breastfeeding[18]. Provider encouragement has been shown to significantly increase breastfeeding initiation, especially among low-income, young, less-educated, or single women[22]. Although breast milk is the best, some mothers choose not to or cannot breastfeed. Health care providers should be sensitive to their needs[18]. Patient demographics rather than physician practice predict low breastfeeding rates[23].

Obstetricians can help clarify misconceptions. Maternal hepatitis B virus (HBV) infection, common in Hong Kong, was one of the reasons for the persistently low breastfeeding rate[24]. It is important to provide appropriate counselling on its safety with regard to mother-to-child transmission of HBV after newborns have received hepatitis B vaccine and immunoglobulin at birth, in order to allay the fear and anxiety of HBV surface antigen–positive mothers[24]. Transmission of hepatitis C through breastfeeding has not been documented.

Intrapartum

Maternal care practices can influence breastfeeding rates. Facilitating immediate skin-to-skin contact between mother and infant and early initiation of breastfeeding are well known measures to improve breastfeeding[25]. Obstetricians should be aware that a prolonged second stage of labour and Caesarean delivery are associated with delayed lactogenesis, while unmedicated spontaneous vaginal delivery is associated with positive breastfeeding outcomes[26]. Mother-friendly care including non-pharmacological pain relief, mobilisation, and presence of partner during labour should be encouraged.

Postpartum

When there are concerns about lactation during the first few days following birth, the infant must be carefully assessed for jaundice, as well as weight loss[25,26]. Parents should be supported in their decision to breastfeed[25]. Lactation consultants can provide valuable support and education for new mothers. Obstetricians can educate women who breastfeed about the option of breast pumps and expressed breast milk[25]. For newborn's excessive weight loss (more than 10% of the birth weight) or neonatal jaundice that requires phototherapy, a paediatric consultation should be arranged.

Infants in the Neonatal Intensive Care Unit

For preterm infants, human milk offers special benefits in host defence, gastrointestinal development, special nutrition, and neurological outcome[1,27,28]. Human milk is associated with improving outcomes of infants in the neonatal intensive care unit (NICU). Yet, mothers in the NICU face difficulties including delayed onset of lactation and insufficient milk. Obstetricians can help mothers make an informed decision to breastfeed in NICU and provide appropriate support[29]. Mothers may prefer pumping milk to feeding from the breast. It is important to select an appropriate breast pump to optimise breast milk supply and prevent injury. As women are unique in their response to individual pumps, one particular pump style or brand may not suit all[30].

Infection

Good hygiene during expression, storage, and feeding should be in place to reduce contamination of human milk with group B streptococcus, methicillin-resistant *Staphylococcus aureus*, or other pathogens[31]. In

the presence of varicella-zoster virus, measles, or herpes on the breast, the mother can temporarily pump and discard her milk until the infection is clear. Human immunodeficiency virus and active tuberculosis before treatment are contra-indications to breastfeeding.

Breast Pain

Some level of breast pain is common in breastfeeding women. Early nipple pain due to suboptimal positioning and latch need to be corrected. For persistent pain, other causes including dermatitis, infection, vasospasm, depression, functional pain, and other rare concerns should be investigated. A careful history should be obtained along with physical examination of the mother's breasts for mass or infection, and the infant's mouth for tongue tie, infection, and abnormal suck mechanics[31]. When women experience breastfeeding problems, they are at risk of postpartum depression, and should be screened and managed appropriately[21]. Treatment of the underlying cause, and working with a lactation consultant are recommended[31].

Medications

The effects of medication on breast milk or feeding should be assessed before being prescribed[26]. Most medications appear in breast milk in very small and safe amounts, and are compatible with breastfeeding[32]. The few exceptions are drugs of abuse, antimetabolites such as chemotherapy, and radioactive compounds. It is not good practice to stop breastfeeding when a new medication is prescribed because little or no information is immediately available. Up-to-date resources are available online, for example, LactMed Drugs and Lactation Database (https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm). Before prescribing, careful assessment of the infant is necessary in all cases, especially in vulnerable infants including those who are preterm, at risk of apnoea, sick, or poorly growing[32]. The use of multiple drugs with similar side-effects of respiratory depression and sedation should be avoided. For contraception, non-hormonal contraceptive methods are preferred as oestrogen-containing oral contraceptives can decrease milk supply. As a second choice, progestogen-only pills may be prescribed.

After prescription, the infant should be monitored for non-specific signs including sedation, drowsiness, or changes in sleep pattern[32]. If non-specific signs occur, proxy markers can be assessed. For example, checking infant prothrombin time if the mother is taking warfarin, or plasma drug levels when taking antiepileptic drugs is recommended.

Policy

The ACOG recommends that obstetrician-gynaecologists and other obstetric care providers should be at the forefront of policy efforts to enable women to breastfeed[21].

Baby-friendly Hospital Initiative

In 1991, the WHO and the United Nations Children's Fund (UNICEF) first launched the Baby-friendly Hospital Initiative (BFHI) aiming to give every baby the best start in life by removing breastfeeding barriers in health facilities and encouraging women to implement the 'Ten Steps to Successful Breastfeeding'[33,34]. Delivery at designated 'baby-friendly' facilities has been shown to increase breastfeeding rates[35]. Different hospitals in Hong Kong have different levels of participation in the BFHI.

Marketing Code

The International Code of Marketing of Breast-milk Substitutes was developed by the WHO and UNICEF in 1981 to protect breastfeeding[36]. Similar coding was drafted in Hong Kong. Some of the relevant rules include: (a) no promotion of products (breastfeeding substitutes, feeding bottles or teats) in or through health care facilities, (b) no gifts or personal samples to health care workers, and (c) health care workers should never pass samples on to mothers[36]. In the past, formula company–produced infant feeding literature, pregnancy literature, and free formula offers were commonly used[12].

Support at the Working Place

Allowing breastfeeding breaks, provision of safe working conditions, and a comfortable, private place to breastfeed and express milk are all effective means of supporting and protecting breastfeeding[37].

Conclusions

Obstetricians, in collaboration with the paediatric provider, lactation consultant and other disciplines, can help promote, protect, and support breastfeeding in the antepartum, intrapartum, and postpartum period. They can also support policy efforts in hospitals and the workplace that enable women to breastfeed. All obstetricians should improve their education about breastfeeding to benefit babies and their mothers.

Declaration

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Towards a Baby-friendly Hospital—Innovation in Midwifery Practice

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Breastfeeding is globally recognised as the optimal feeding to nourish and nurture infants. World Health Organization develops the Baby-friendly Hospital Initiative (BFHI) for breastfeeding support. The BFHI contributes to improving the exclusive breastfeeding worldwide and, coupled with support throughout the health system, can help mothers sustain exclusive breastfeeding. Although the breastfeeding initiation has achieved a substantial increase since last decade in Hong Kong, the exclusive breastfeeding prevalence is below the WHO recommendation. Increasing breastfeeding exclusivity and duration are global public health imperatives. Midwives play a key role to strengthen breastfeeding and enhance mothers' confidence in breastfeeding. We implement innovative evidence-based midwifery care on infant feeding education, mother-baby friendly childbirth practices and develop integrated infant feeding service. Although various challenges are faced in the journey of baby-friendly initiatives, midwives work collaboratively with other stakeholders to uphold the support policy and overcome barriers towards baby-friendly designation.
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Keywords: Breast feeding; Feeding behavior; Infant, newborn

Introduction

Breastfeeding is globally recognised as the optimal feeding method to nourish and nurture infants. Its desirable effects and benefits on growth, immunity, and cognitive development[1] appear to be dose-dependent on exclusiveness and duration. It is a priority and is essential to public health. According to the World Health Organization (WHO) and the American Academy of Pediatrics, exclusive breastfeeding is the gold standard of successful breastfeeding. Studies indicate that Hong Kong infants who exclusively breastfeed for ≥4 months have 27% fewer doctor visits for respiratory infections and 21% fewer visits for gastrointestinal infections[2,3].

Although the breastfeeding initiation rate in Hong Kong has achieved a substantial increase in the last decade from 57.58% in 2005 to 86.16% in 2015[4] (Figure 1), the exclusive breastfeeding rate remains considerably below the WHO target. A local breastfeeding survey from the Hospital Authority and Department of Health reported average exclusive breastfeeding rates at 1 month postpartum and at 6 months as 22% and 2.3%, respectively in 2012[5] (Figure 2); such figures are far behind the universal goal of 75% and 25.5%. Studies indicate that many mothers' premature discontinuation of breastfeeding is preventable with effective care. There is evidence that increased breastfeeding exclusivity and duration can be protected, promoted, and supported through coordinated implementation of hospital policies and evidence-based practices[3,6].

The Baby-friendly Hospital Initiative (BFHI) has been launched worldwide by the WHO and United Nations Children's Emergency Fund (UNICEF). It aims to improve hospital practices and enhance breastfeeding rates by promoting the worldwide adoption of the Ten Steps to Successful Breastfeeding (Table) and compliance with the International Code of Marketing of Breast-milk Substitutes[7,8]. In recent years, the opportunity to enhance the promotion of breastfeeding has been introduced as the Hospital Authority pursues the BFHI. According to a midwifery series[9], the practice of midwifery is defined as skilled, knowledgeable, and compassionate care for childbearing women, newborn infants, and families across the continuum throughout prepregnancy, postpartum, and the early weeks of life. Midwifery compassionate care consists of courage, communication, competence, commitment, compassion, and caring in providing women-centred care, informed choice, autonomy, and continuous care to lactating mothers and their families. Midwives

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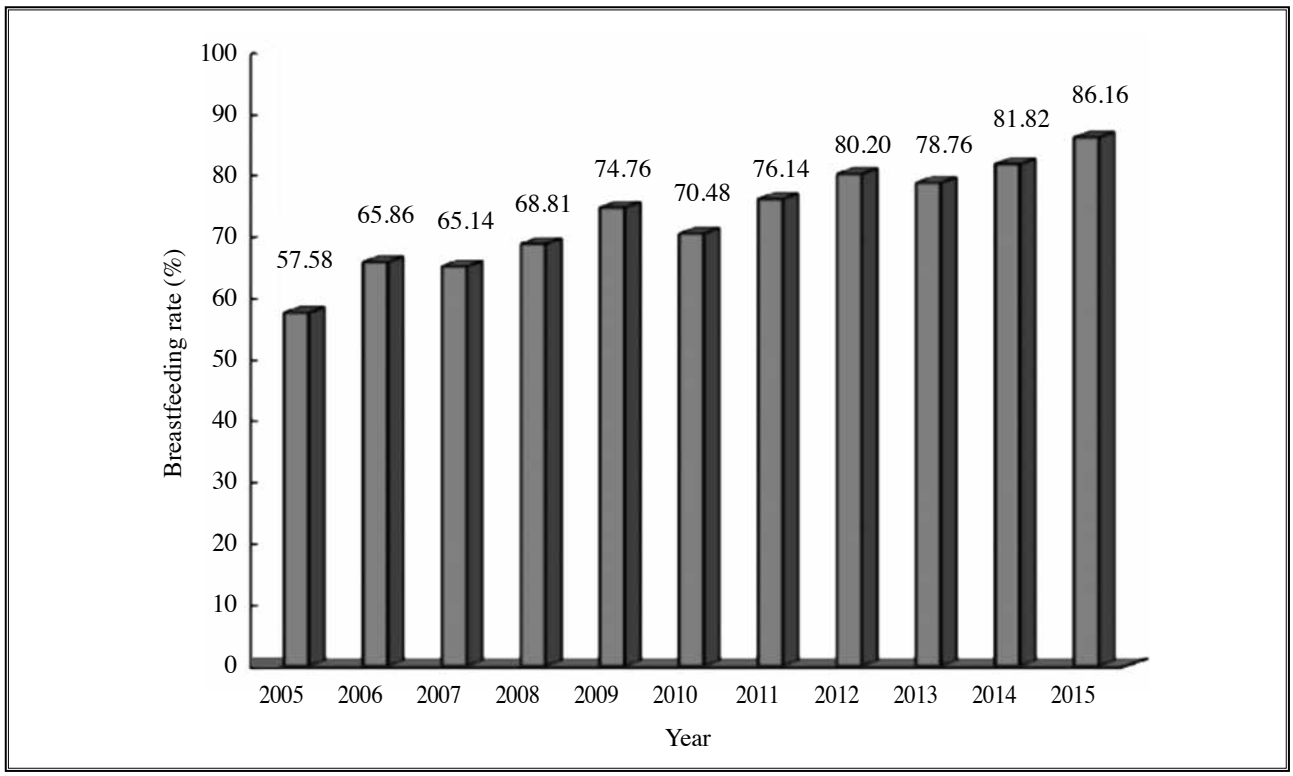

Figure 1. The overall mean breastfeeding rates upon hospital discharge from 2005 to 2015[4]

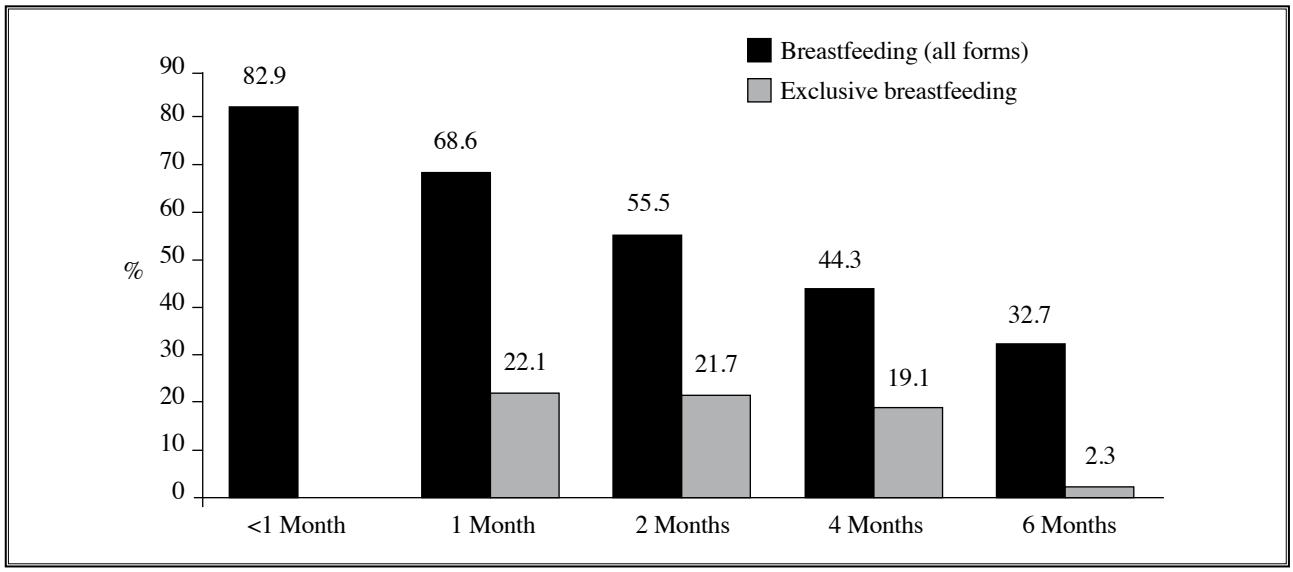

Figure 2. Breastfeeding statistics in 2012[5]

work in partnership with women to strengthen women's own capabilities to care for themselves and their family. They also play a key role in concerted efforts to implement breastfeeding support policies and mother-baby friendly practices in accordance with global criteria to enhance positive breastfeeding experiences, as well as breastfeeding exclusivity and duration.

Innovation in Midwifery Practice

Infant Feeding Education

Education for pregnant women about infant feeding should be an ongoing process. It commences at the first antenatal booking and should continue throughout pregnancy up to the hospital stay during the postpartum period.

Table. Ten Steps to Successful Breastfeeding[7]

1.	Have a written breastfeeding policy that is routinely communicated to all health care staff.
2.	Train all health care staff in skills necessary to implement this policy.
3.	Inform all pregnant women about the benefits and management of breastfeeding.
4.	Help mothers initiate breastfeeding within half an hour of birth.
5.	Show mothers how to breastfeed and how to maintain lactation even if they should be separated from their infants.
6.	Give newborn infants no food or drink other than breast milk, unless medically indicated.
7.	Practise rooming-in: Allow mothers and infants to remain together 24 hours a day.
8.	Encourage breastfeeding on demand.
9.	Give no artificial teat or pacifiers (also called dummies or soothers) to breastfeeding infants.
10.	Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from hospitals or clinics.

In the past, the majority of local antenatal education was conducted in a big group and women seldom had a chance to raise or discuss their concerns. In order to strengthen education about infant feeding, individual counselling and small group discussions should be coordinated by midwives. Two-way communication with mothers helps to create a trusting and caring relationship[9-12]. Antenatal infant feeding education can be innovative and women-centred. It includes increased numbers of morning and evening classes, engagement of family members, and free access to teaching materials on the website, flyers, DVDs, and breastfeeding education packages. In small group discussions and individual counselling, midwives are able to demonstrate empathy, actively listen to women's feedback, and encourage them to be aware of their own capacities. They are empowered to make decisions and have a sense of control to access information and lactation support. Antenatal education should also cover the prerequisites of BFHI, such as skills in hand expression, responsive feeding cues, handling of expressed breast milk, the risks of giving supplements in the first 6 months, and optimal positioning and attachment of the newborn.

During the classes, trained midwives coach mothers using breast models and dolls. Midwives act as skilled companions to share successful breastfeeding experiences and offer anticipatory guidance to women. Mothers are informed about continuity of care if they encounter any breastfeeding difficulties after birth. Midwives make a concerted effort to enhance breastfeeding exclusivity and build mothers' confidence in breastfeeding.

Safe preparation and feeding of infant formula is discussed individually if the mother opts for formula feeding in the postpartum period.

Mother-friendly Childbirth Practice

In 1994, 31 individuals and 26 national organisations in the United States set up the Coalition for Improving Maternity Services[13]. It launched the Mother-Friendly Childbirth Initiative (MFCI) and the Ten Steps of the MFCI for mother-friendly hospitals, birth centres, and home birth services in 1996. They are listed below:

1. Offers all birthing mothers unrestricted access to birth companions, labour support, and professional midwifery care.
2. Provides accurate, descriptive, statistical information about birth care practices.
3. Provides culturally competent care.
4. Provides the birthing woman with freedom of movement to walk, move, and adopt positions of her choice.
5. Has clearly defined policies, procedures for collaboration, consultation, links to community resources.
6. Does not routinely employ practices, procedures unsupported by scientific evidence.
7. Educates staff in non-drug methods of pain relief and does not promote the use of analgesics, or anaesthetic drugs.
8. Encourages all mothers, families to touch, hold, breastfeed, care for their babies.
9. Discourages nonreligious circumcision of the newborn.
10. Strives to achieve the WHO/UNICEF Ten Steps of the BFHI to promote successful breastfeeding.

Regarding Step 1, studies reveal that birth companions can provide psychological support to the birthing woman and increase their confidence and ability to give birth[14]. Continuous labour support also facilitates

the physiological labour process and women's feelings of control and competence. As a result, the need for obstetric intervention may be reduced[14]. In view of the known benefits, husbands or significant others are encouraged to accompany the birthing women during labour and birth until transfer to the postnatal ward. During labour, apart from providing psychological support, the birth companion also gives physical support such as massage for the women and providing help to mobilise, use the birth ball or adopt different positions. This support has a positive effect on the birth process. In addition, in order to create a sense of peace, a dimly lit birthing room is prepared and a quiet environment encouraged. Women are also supported by named midwives throughout their labour and birth.

For Step 4, research indicates that mobilisation during active labour may shorten the process and improve birth outcome[15]. At present in some hospitals, birthing women who are low risk are encouraged to move around during active labour and various labour and birth positions are introduced to them during the antenatal period. Instead of being confined to bed, or using the lithotomy or semi-recumbent position, women can choose the most suitable position for themselves such as sitting, kneeling, adopting an all fours position or lying on their side.

For Step 6, evidence indicates keeping a labouring woman nil by mouth causes dehydration and undermines her morale[16]. In Hong Kong, it has been routine practice in many maternity institutes that women in labour are not allowed to eat or drink. Low-risk birthing women should be encouraged to eat and drink as one of the methods to facilitate spontaneous births. By supporting this management, the chance of mothers and infants needing to be separated following interventions may be reduced after birth, and uninterrupted skin-to-skin contact (SSC) and breastfeeding can be initiated immediately at birth.

Episiotomy has been a routine practice in the past. Nonetheless, there is evidence that it is not routinely necessary and does not reduce the chance of a third- or fourth-degree perineal tear[17]. Midwives in the public sector no longer perform routine episiotomy. Likewise, interventions such as rupture of membranes, vaginal examination, continuous fetal heart monitoring, intravenous infusion, and suctioning of the newborn at birth are only performed if indicated.

For Step 7, an antenatal childbirth massage teaching programme has been launched. LK Massage Programme was initially developed through two research projects and has been launched in the United Kingdom[18]. It is an intervention that involves the use of specific massage techniques and touch in combination with slow controlled breathing. It also promotes upright positions during active labour and the involvement of birthing partner or midwife. The first phase of this Programme has been designed to complement maternal/paternal adaptations to late pregnancy, circadian uterine activation, spontaneous labour and birth, and immediate undisturbed SSC between the mother-infant dyads, and enhances mutual attachment and lactation[19]. It helps the women in labour to relax and cope with uterine contractions. This evidence-based programme promotes natural physiological labour and birth. It suggests that regular massage with relaxation techniques from late pregnancy to birth is an acceptable coping strategy in labour pain. It was introduced to midwives in Hong Kong in 2009.

Studies show that Pethidine leads to maternal sedation and disorientation, depresses neonatal respiration, and hinders thermoregulation and the initiation of rooting and suckling reflexes[20,21]. Infants exposed to Pethidine take longer to identify their mother's smell and coordinate suckling, and swallowing reflexes, and these effects last for up to 72 hours after birth[22].

Newborn infants exposed to epidural analgesia have a higher chance of respiratory depression, and take longer to respond to maternal temperature regulation, recognise maternal smell, respond to her voice and coordinate suckling, and swallowing reflexes. These effects are more obvious in those exposed to higher doses of fentanyl[23].

Currently, to provide labouring women with an alternative choice, non-drug labour pain relief such as breathing exercises, birth ball, LK Massage Programme, aromatherapy, music and warm compresses are provided in most public maternity units. They are safe for women and fetuses[24].

Early Skin-to-skin Contact Following Birth for at Least an Hour

The Cochrane systematic reviews[25] suggest that immediate contact between mother and newborn can improve breastfeeding outcomes, maternal affectionate behaviour, attachment, and shorten crying time. The literature concludes that there are no adverse effects of SSC[25]. It is simple and needs minimal financial resources. It promotes rest, reduces stress and lowers stress hormones, encouraging early mother-infant bonding, protecting infants from harmful germs, and easing their transition

to extrauterine life[26,27]. Some observational studies have determined that extended and uninterrupted early SSC influences effective suckling[28]. Evidence shows that SSC immediately after birth accompanied by suckling at the breast enhances a neonate's recognition of maternal milk odour, and has enduring effects on breastfeeding[29]. Successful SSC experiences are associated with breastfeeding exclusivity and demonstrate a dose-response relationship[28,30].

In recent years, healthy newborns have been placed on their mother's abdomen and chest to allow SSC immediately following both vaginal and Caesarean births, and left to find their way to the mother's breast. They are allowed to stay snuggled for at least an hour. Routine procedures such as weighing, measuring, and physical examination are delayed until after this period.

Rooming-in—Allowing Mothers-infant Dyad to Remain together 24 Hours a Day

Historically in birthing hospitals, it was routine practice to keep a healthy newborn infant in an incubator for several hours and then in the nursery after the mother transferred to the postnatal ward, in order to provide better observation and promote improved maternal sleep. Infants who had had uncomplicated vaginal births would be returned to their mothers after an observation period. Nonetheless, babies born by Caesarean section were cared for in the nursery for at least 2 days following birth. Current research reveals that it is optimal for mothers and infants to stay together continuously during the day and night (rooming-in) after birth unless there are medical reasons for the contrary[31,32]. Separation of a mother and her baby may have a harmful effect on their relationship and on breastfeeding success[33]. Mothers who are with their infants for longer periods of time, particularly in SSC, have higher scores on tests that estimate the strength of a mother's attachment to her infant. By staying together, mothers learn their infants' needs and how to care for and comfort them quickly[34-36]. In addition, mothers rooming-in with their babies and those with more SSC produce more breast milk[37], breastfeed longer, and are more likely to breastfeed exclusively compared with those who have limited contact with their infant[28,30,38]. The infants also cry less, are soothed more quickly, and spend more time sleeping quietly[26-28].

In recent years, the practice of 24-hour rooming-in has been implemented for healthy infants and mothers in public maternity hospitals, and frequent extended SSC is encouraged. Every effort is made to unite mother and baby as soon as possible for those mothers and babies who require obstetric interventions. This change in policy complies with the global criteria and current evidence-based practice.

Supporting Mothers with Early Breastfeeding and Establishing Lactation

Midwives who support mothers with early breastfeeding and lactation need to identify the correct attachment and the optimal position for the mother to breastfeed. Mothers are taught how to massage their breasts as well as hand expressing milk, recognise feeding cues, and the ways to establish lactation by effective suckling.

Developing the Infant Feeding Team for Breastfeeding Support

The Global Strategy for Infant and Young Child Feeding[38] states that breastfeeding mothers should be able to have access to certified lactation consultants who can build confidence, improve feeding techniques, and prevent/resolve breastfeeding problems. The certified lactation consultants in the infant feeding team carry out breastfeeding assessment and lactation consultations. They also monitor breastfeeding prevalence, coordinate breastfeeding promotion, deliver lactation training for health care professionals, facilitate interdisciplinary collaboration, and lead breastfeeding practices and support lactating mothers' needs.

Lactation support by lactation consultants includes breastfeeding coaching, lactation management, telephone follow-up after hospital discharge, and a lactation clinic. Within the lactation clinic, mothers are helped with attachment, positioning, poor breast milk removal, and are provided support and advice when there is poor baby weight gain. A local retrospective case review carried out in one of the birthing hospitals in 2013 suggested that the expert support from lactation consultants during hospital admission helped mothers to sustain breastfeeding and could lead to higher breastfeeding exclusivity at 1 week and 4 weeks postpartum. Mothers reported that support from lactation consultants was significantly helpful in sustaining breastfeeding[39].

Conclusions

Promoting breastfeeding is a public health priority. Midwives have a key role to play and work collaboratively with other stakeholders to support breastfeeding and the establishment of a baby-friendly hospital in accordance

with global criteria. Transforming breastfeeding is complex and midwives face multiple barriers. Nonetheless, we are confident that courage, caring, and intuition will overcome the profound challenges to achieve comprehensive breastfeeding success in the coming years. Let us join together to provide compassionate midwifery care to our mothers and their infants.

Declaration

All authors have disclosed no conflicts of interest.

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A Review of Current Legislation on Milk Formula Advertising for Infants and Young Children in Hong Kong

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The World Health Organization published an International Code of Marketing of Breast-milk Substitutes in 1981 to emphasise the merits of exclusive breastfeeding. As Hong Kong has joined the code on a voluntary basis, this Code of practice is not backed up by formal legislation and is thus not legally binding. Over the past decades, milk formula advertising has been so successful that acceptance of formula milk prevail from hospital to home. Pro-breastfeeding advocates generally argue that milk formula advertising has become a major obstacle in boosting breastfeeding rates. This article reviews the current legislation on milk formula advertising for infants and young children in Hong Kong, and the attempts of the government to enhance such legislation.
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Introduction

Use of formula milk for infant feeding is commonplace among mothers in Hong Kong. Although the rates of initiation and duration of breastfeeding have increased over the past two to three decades, a significant proportion of Hong Kong mothers continue to use formula milk as the main food for babies from birth, and the majority as the main food or in addition to breast milk by around 2 months. By 6 months most babies are fully formula fed[1]. The World Health Organization (WHO) published an International Code of Marketing of Breast-milk Substitutes[2] in 1981 to emphasise the merits of exclusive breastfeeding; it not only recommends mothers to exclusively breastfeed for 26 weeks, but also provides a set of marketing rules that aim to ensure that all parents are protected from commercial exploitation and receive unbiased and appropriate information[3]. More than 80 nations have adopted the 34-year-old WHO Code (Hong Kong has joined the Code voluntarily)[4] that calls for education about "the benefits and superiority of breastfeeding" and adequate product labelling, and advises that "manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code". Local surveys have sought specifically to assess the incidence of this practice, and a consistent finding is that breaches to these policy recommendations in Hong Kong are banal[1,5]. At present, there is a voluntary consensus among all local publishers and media not to advertise infant formulae (for babies from birth to 6 months), while the Department of Health will routinely issue a written warning to advertisers or suppliers who violate this consensus. It must be recognised nonetheless that there is no formal legislation banning advertising of infant formulae. It is also clear that no such agreement can be made for products targeted at children over 6 months of age.

The promotion of breast milk substitutes in commercial advertisements has long been recognised to place commercial pressure on baby feeding decisions and undermine breastfeeding. Advocates for breastfeeding have argued for restrictions on the advertising of formula milk or follow-up preparations and in some cases for a complete and effective ban in Hong Kong. The logic used is that whereas information informs, advertising is not neutral information, as it solely tries to persuade one to buy a product. Despite the Department of Health's consistent and strong support for the Code, given the lack of legislation in Hong Kong, implementation of this code has so far been largely ineffective and controversial.

Undoubtedly, the Department of Health has been a strong advocate for breastfeeding in the past, with campaigns being launched through the Family Health Service of the Department of Health. Public hospitals under the Hospital Authority are pledging to be baby-

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friendly hospitals[3,6], and this requires adherence to a set of strict protocols dictated by the WHO. Despite all these efforts, breastfeeding rates have remained low compared with many other western countries. It can be argued that there are many contributing factors associated with this low breastfeeding rate in Hong Kong, including labour laws that allow only 10 weeks of maternity leave compared with much more liberal peripartum leave in certain European jurisdictions, as well as widely quoted studies that show an association of failure to breastfeed with poor health, work pressure, lack of breastfeeding facilities, and sometimes a lack of support from partners. Nevertheless, the insufficient laws to restrict advertising of infant formula milk and associated products have become one of the most critical issues believed to curtail the promotion of breastfeeding. This article serves to review the existing laws in Hong Kong that can be applied to restrict excessive and inappropriate advertising of these products, and the new developments in this area.

Current Legislation in Hong Kong

The legislative ordinances in Hong Kong normally refer to formula products and foods intended for infants and young children (IYC) under the age of 36 months. The formula products may be subdivided into infant formula (for use from birth up to the introduction of appropriate complementary feeding, usually around 6 months) and follow-on formula (beyond 6 months)[7]. Food intended for IYC include processed cereal-based food and baby food. It is obvious that most of the discussion relating to the impact on breastfeeding refers to infant formula for use from birth and follow-on formula for use beyond 6 months, as these will have the greatest impact on breastfeeding rates in Hong Kong mothers.

Section 54 of the Public Health and Municipal Services Ordinance (Cap. 132) stipulates that all food for sale must be fit for human consumption. This ordinance applies to all food products including formula products and foods intended for IYC under the age of 36 months. Nonetheless, there are no specific provisions in Cap. 132 governing the requirements and standards for nutritional composition of these formula products and foods intended for IYC under the age of 36 months. Section 61 of the same Ordinance also offers broad protection against misleading nutritional claims, as it stipulates that any person who sells or displays any food for sale that is presented with a label that falsely describes the food, or is calculated to mislead as to its nature, substance or quality, shall be guilty of an offence. Regrettably the threshold for prosecution under this section is in general high, and unless the products are counterfeit or fraud and directly harmful to health, there is a need for the prosecution to prove that the label in question is intentionally misleading or false.

The Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) require prepackaged foods for people aged 36 months or above to provide nutritional information on their labels ("general prepackaged foods"), but do not cover formula products and foods intended for IYC under the age of 36 months. Thus, nutrition and health claims made on formula and IYC products are outside the scope of the Nutrition Labelling Scheme[8]. In addition, even when many of these IYC products sold in Hong Kong carry nutrition labels, the information presented and the formats used are not consistent.

The Food and Drugs (Composition and Labelling) [Amendment] (No. 2) Regulation 2014 was published in the Gazette on 13 June 2014 with a view to better regulating the nutritional composition of infant formula, as well as nutrition labelling of formula products and IYC foods[9]. On 22 October 2014, the Legislative Council completed its vetting of this amendment that came into force on 13 December 2015 (after a grace period of 18 months) for infant formula and on 13 June 2016 (after a grace period of 24 months) for follow-on formula and IYC foods. This regulation amends Cap. 132 sub. leg. W ("the principal Regulations") to provide for: (a) the standards of composition of infant formulae; (b) the nutrition labelling requirements of infant formulae, follow-on formulae, and prepackaged food for IYC; (c) the items that are exempt from the standards or requirements; and (d) the offences and penalties for non-compliance with the standards and requirements. In this amendment, definitions of many technical terms are updated, including nutrient, vitamins A, C, E and K, folic acid, niacin, information about formula for special medical purposes for IYC, infant formula, and prepackaged food for IYC. Nonetheless, because of the complexity and controversies involved, the regulation of nutrition and health claims for these products has not been included in this legislative amendment.

The Undesirable Medical Advertisements Ordinance (Cap. 231) under the purview of the Department of Health prohibits any person from publishing or causing to be published any advertisements likely to lead to the use of, inter alia, any medicine for the purpose of treating human beings for, or preventing them from contracting specified diseases or conditions. It also regulates the advertising of specified claims for orally consumed products (OCP). Nonetheless, OCP usually include oral medicines such as

pills, capsules, tablets, granules, powder, semi-solid or in liquor, but do not normally include products that are customarily consumed only as food or drink. Therefore, nutrition and health claims on formula products and IYC foods are generally not covered by Cap. 231 as these products do not fall within the definition of medicine or that of OCP under Cap. 231. Specifically, whether an infant formula product and IYC food is considered a medicine or OCP would have to be decided on a case-by-case basis, taking into account actual circumstances of the case.

The Trade Descriptions Ordinance (Cap. 362) under the purview of the Customs and Excise Department prohibits, inter alia, false trade descriptions, false, misleading or incomplete information, false marks and mis-statements in respect of goods provided in the course of trade. Depending on how the nutrition and health claims for formula products and IYC foods are made, such claims can be governed by Cap. 362. Nonetheless, as with Cap. 132, the threshold for prosecution under Cap. 362 is high, requiring, among other things, expert evidence, including that to be tendered by the Centre for Food Safety, to prove that the trade description is false to a material degree[10].

Legislation to tackle false advertising via broadcasting, according to the Generic Code of Practice on Television Advertising Standards, issued by the Communications Authority pursuant to section 3 of the Broadcasting Ordinance (Cap. 562), dictates that all factual claims and best-selling claims should be capable of substantiation. Nevertheless, this legislation basically refers to the methods of advertising and not to the products themselves.

It is clear that there is currently no direct legislation on the advertising and health claims of infant formula and follow-on formula in Hong Kong. Any legislation that can be brought against such advertising can only make use of false labelling or false trade claims. In particular, such legislation cannot effectively regulate the nutrition and health claims made on formula products and IYC foods. The recent Government consultation document in early 2015[10] concluded that:

1. Legislation that governs general food labelling and advertisement is not applicable to the nutrition and health claims made on formula products and IYC foods (e.g. Cap. 132W and the Food and Drugs [Composition and Labelling] (Amendment) [No. 2] Regulation 2014).
2. For legislation that is applicable to the nutrition and health claims on formula products and IYC foods, they lack specific provisions on the claims made on these products. It can be expected that a great deal of effort and research have to be undertaken by the Centre for Food Safety to establish the truthfulness of a nutrition and health claim before a case for prosecution can be established (e.g. section 61 of Cap. 132 and Cap. 362)[5].
3. The threshold for prosecution under such legislation is high, requiring the prosecution to prove with sufficient evidence that the label in question is intentionally misleading or false (section 61 of Cap. 132) or that the trade description concerned is false to a material degree (as in Cap. 362), so that the chances of successive prosecution will be anticipated to be low.

Recent Developments

The Hong Kong Code

In view of these limitations of the current legislation, the Government set up the Taskforce on Hong Kong Code of Marketing of Breastmilk Substitutes in June 2010 under the Department of Health to develop and promulgate a code of marketing and quality of formula milk and related products for IYC, i.e. the Hong Kong Code. In the course of drafting the code, the Taskforce held meetings with representatives of six multinational formula milk companies, and made reference to the WHO Code 1981, and relevant subsequent World Health Assembly resolution that clarified the WHO Code and sought to bring it up-to-date with scientific developments and evolving marketing strategies. The Taskforce completed the drafting of the Hong Kong Code in October 2012 and the subsequent public consultation received a total of over 150 submissions by early 2014. Views were diversified as to the degree of control particularly over nutrient and health claims[11]. The consultation on the Hong Kong Code was reported to the Legislative Council in July 2014[12].

The 2015 Consultation on Nutrition and Health Claims

Government proposed a more advanced regulatory framework for nutritional and health claims about infant formula and associated products in January 2015. The proposal in this new consultation is based on the principles of the Codex Alimentarius Commission (Codex) established in 1963 by the Food and Agriculture Organization of the United Nations and WHO to develop food standards, guidelines, and other codes of practice to protect consumer health and ensure fair practices in the food trade and sales.

According to the Codex guidelines, a nutrition claim is any representation that states, suggests, or implies that a food has particular nutritional properties including but not limited to energy value and the content of protein,

fat, carbohydrates, vitamins, and minerals. These nutrition claims may be a nutrient content claim, i.e. that the nutrient contained in the product is at a certain level; or a nutrient comparative claim, that the level of nutrient in the product is, for instance, less than, more than, increased, or reduced compared with another food or breast milk.

According to the Codex, a health claim is defined as any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Commonly seen health claims in formula milk advertisements include: (a) nutrient function claims, e.g. phospholipids are essential for the functioning of brain cells and brain development; (b) other function claims that consumption of the product has specific beneficial effects, e.g. probiotics help to regulate bowel and digestive function; and (c) reduction of disease risk claim, e.g. that formula fortified with iron will reduce the risk of anaemia.

The Consultation paper[10] surveyed the regulations in different countries on such nutrition and health claims and found a complicated and varying picture across these different legislations, with different allowances for infant formula, follow-on formula, and IYC foods, reflecting the controversial nature of this issue and the lack of a universally agreed standard. The Government has come up with the following five overarching principles to govern the scope of the regulatory framework:

1. Nutrition claims (including both nutrient content and nutrient comparative claims) should be prohibited for infant formula.
2. Reduction of disease claims should be prohibited in formula products and IYC foods.
3. Nutrition claims including both nutrient content and nutrient comparative claims, and nutrient function claims should be permitted for IYC foods.
4. Nutrients or constituents permitted to be the subjects of claims should be of high importance to the health of IYC.
5. Nutrition and health claims should meet specific content conditions and health claims should be scientifically substantiated and have undergone credible evaluation processes.

It is believed that the first three overarching principles would be more likely to be generally accepted. The other options that are open for debate within this Consultation will then be nutrient function claims for infant formula, nutrient claims and nutrient function claims for follow-on formula, and other function claims for formula products and IYC foods. The Consultation paper calls for the public's views on whether a restrictive approach (whereby all the above claims would be prohibited) or an inclusive approach (whereby all of the above claims would be allowed), or somewhere in between these two stands should be accepted as the basic regulatory framework for Hong Kong. While the Consultation period has formally been completed for over 1 year at the time of writing, no resolutions have yet been proposed by the government.

The Debate

Pro-breastfeeding groups have advocated more stringent regulation of all nutrition and health claims, and have argued that the exaggerated claims in the advertisements for many of these products have misled parents and the public about their superior or at least non-inferior value compared with breastfeeding. The trade and producers nonetheless would argue that such stringent control is unnecessary, as the nutrition and health claims are well based on scientific data and will provide useful information to consumers, and that in order to substantiate these claims, the trade will have great incentive to invest in product development and research.

By the end of the consultation on 27 April 2015, many had openly expressed their views. Those supporting a restrictive approach include the Hong Kong College of Paediatricians[13] and the School of Nursing, the University of Hong Kong[14]. The Hong Kong Infant and Young Child Nutrition Association[15] seems to support a more midway stand between the restrictive and inclusive approach. Opposing views would argue that this Hong Kong code would violate World Trade Organization law[16], or would set a dangerous precedent of government over-intervention. Some of the arguments put forward are equally rigorous, "This drastic measure will endanger consumer access to information and commercial freedom of speech, both of which are cornerstones of Hong Kong's free market competitiveness…Over-regulation discourages reputable players from Hong Kong, hurts our free market reputation, and adversely impacts on employment opportunities and consumer choice"[17]. Indeed, the resistance from milk formulae suppliers and traders has also been intense, and vigorous lobbying has been underway to deter the establishment from producing any formal legal regulatory framework.

Solutions and Summary

The very frequent consultations that the Government has proposed in recent years on the regulation of infant formula milk products are unprecedented. The public debate is also intense, with professional bodies

and pro-breastfeeding advocates fighting for a more and more restrictive approach, and the trade putting up the greatest resistance to protect its commercial interests. The confrontation is not unlike that seen some decades ago in the tobacco industry, although it is dangerous to draw any analogy between infant formula and tobacco, with their distinctly different effects on health. Public receptiveness to the concept of breastfeeding as the best option will be a key factor for the successful passing of more restrictive legislation, and this tide is most likely to be adamantly resisted by the trade. Under existing legislation, actual prosecution for false advertising or unsubstantiated claims/labelling is anticipated to be few and far between, and the establishment of direct and restrictive legislation would have served its purpose to keep misleading and exaggerated advertising in check. The Government's proposed middle road approach between no direct legislation and complete banning of commercial propaganda seems to have struck a balance between all stakeholders, but is certain to involve vigorous power play between political and financial stakeholders. Given the uncertainties and subtleness of this road forward, perhaps a more direct and less confrontational approach would be for the government to simply focus on enhancing the promotion of breastfeeding to the public, so that through education of consumers, change of consumer behaviour to more baby-friendly practices would overwhelm any effects of milk formula advertising.

Declaration

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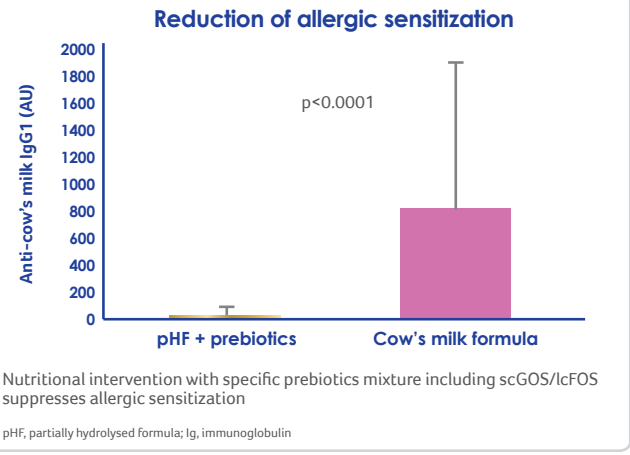
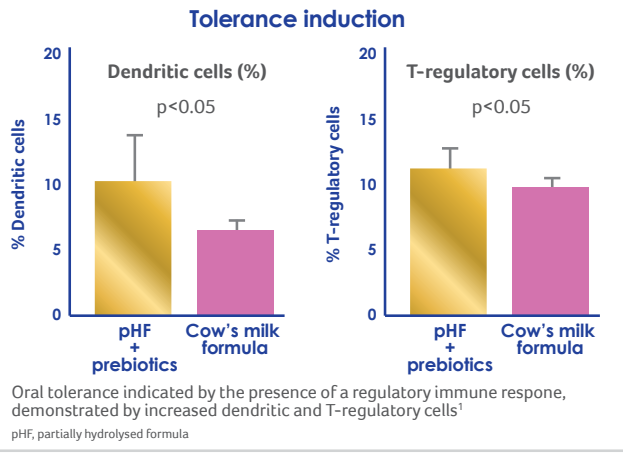


Nutritional intervention with specific prebiotics mixture including scGOS/lcFOS suppresses allergic sensitization

pHF, partially hydrolysed formula; Ig, immunoglobulin

2 Contributes to oral tolerance of cow's milk protein[1]



Oral tolerance indicated by the presence of a regulatory immune respone, demonstrated by increased dendritic and T-regulatory cells[1]

pHF, partially hydrolysed formula

Infants at an increased risk of allergic disease were randomly assigned to receive partially hydrolysed formula supplemented with a specific mixture of oligosaccharide prebiotics or standard cow's milk formula for the first 6 months of life if parents decided to stop or supplement breastfeeding in the first 18 weeks (n=1,047); samples were obtained from infants at the age of 6 months.

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Important Notice:
Breastfeeding is best for babies and provides the best start in life. It is important that, in preparation for and during breastfeeding, pregnant women eat a healthy, balanced diet. Combined breast and bottle feeding in the first weeks of life may reduce the supply of mothers' own breast milk, and reversing the decision not to breastfeed is difficult. The social and financial implications of using infant formula should be considered. Improper use of an infant milk or inappropriate foods or feeding methods may present a health hazard. If mothers use infant formula, they should follow the manufacturer's instructions for use carefully – failure to follow the instructions may make their babies ill. It is recommended for mothers to consult doctors, midwives or health visitors for advice about feeding their babies.

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