A RETROSPECTIVE REVIEW OF OPERATIVE VAGINAL DELIVERY AMONG INDIAN PATIENTS IN HOSPITAL TUANKU JA'AFAR SEREMBAN: MATERNAL AND FETAL OUTCOMES

DR NUR FADHILAH BINTI AB GHANI

DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF MEDICINE (OBSTETRICS AND GYNAECOLOGY)

UNIVERSITI SAINS MALAYSIA

2023

CHAPTER 1

PRELIMENARIES

TABLE OF CONTENT

1.2 ACKNOWLEDGEMENT

Greatest praise to Allah S.W.T, the Al-Mighty for His blessing and generosity provided me with strength and courage throughout the entire process of this dissertation completion.

I own my deepest gratitude to my supervisors, Prof Dr Nik Ahmad Zuky bin Nik Lah, Feto-Maternal Consultant, Consultant Obstetrics and Gynaecology, and Dr Engku Husna binti Engku Ismail, Lecturer Obstetrics and Gynaecology of Department of Obstetrics and Gynaecolgy, University Sains Malaysia, for their great support, advice, knowledge and guidance. Many thanks to all lecturers who contributed a lot during my master training.

Most importantly, my backbone support, my beloved husband, Dr Mohd Azam Imran bin Mahalim, my beloved parents Haji Ab Ghani bin Haji Mat Daud and Hajah Sharifah binti Deris, my beloved parents in-law, Dr Mahalim bin Taib and Dr Darina binti Ariffin, for their constant encouragement, understanding, patience and pray. To the most wonderful son, Muhammad Amsyar Fayyadh bin Mohd Azam Imran, thank you for your presence and greatest love I have ever known.

Finally, I would like to thank the staff in the record office for helping me with tracing all the records without fail. Not to forget, any individuals who were indirectly involved in the completion of this study.

Dr Nur Fadhilah binti Ab Ghani

MMED O&G USM

1.3 LIST OF ABBREVIATION

OVD	Operative Vaginal Delivery
BMI	Body Mass Index
LSCS	Lower Segment Caesarean Section
HTJS	Hospital Tuanku Ja'afar Seremban
OA	Occiput anterior
OP	Occiput posterior
OT	Occiput transverse
SAH	Subaponeurotic haemorrhage
RCOG	Royal College of Obstetricians and Gynaecologists
ACOG	The American College of Obstetricians and Gynaecologists
WHO	World Health Organisation

1.4 DEFINITION OF TERMINOLOGY

Operative vaginal delivery	Vaginal delivery of baby performed with the help of forceps or vacuum device
Race Indian	Patient's name with "a/p", the race stated as Indian in registration details
Maternal age	Completed years at time of delivery
Gestational age	Estimated from the date of last menstrual period and amended using early ultrasound measurement
Prolonged second stage	>1 hour for primigravida, >30 minutes for multigravida
Body mass index	Weight (kg)/height ($m^{2),}$ categorised as
	Underweight BMI <18.5
	Normal BMI 18.5-24.9
	Overweight BMI 25-29.9
	Obese BMI >30

Apgar score	A method of determining an infant's condition at birth by screening heart rate, respiratory effort, muscle tone, reflex irritability, and colour. The infants are score from 0 to 2 on each of the five aspects, the highest possible score being 10. The purpose is to determine the need for resuscitation and evaluate the effectiveness of resuscitation efforts
	Score 7-9 free from immediate distress
	Score 4-6 moderately depressed, may require additional resuscitation measured
	Score 0-3 severely depressed, immediate resuscitation required
Cephalhematoma	A collection of blood between the skull and the periosteum and is delineated by suture line
Caput	Oedema of the scalp skin and crosses suture line
Subaponeurotic haemorrhage	Bleeding under the aponeurosis of the scalp resulting from trauma to the blood vessels, crossing the space from the skull to the overlying scalp

1.5 ABSTRAK

Latar belakang: Istilah kelahiran secara vakum dan forsep merujuk kepada kelahiran di mana pengendali menggunakan alat bantuan untuk membantu kelahiran bayi. Terdapat dua alat bantuan yang sering digunakan iaitu vakum dan forsep. Penggunanna kedua-dua alat tersebut akan menyebabkan risiko kepada ibu dan bayi. Tujuan kajian ini adalah untuk mengenal pasti risiko yang berlaku ke atas ibu dan bayi dalam kalangan pesakit wanita berbangsa India yang melahirkan bayi melalui kaedah vakum dan forsep di Hospital Tuanku Ja'afar, Seremban.

Kaedah Kajian: Satu kajian retrospektif telah dijalankan melalui semakan 269 rekod perubatan pesakit di kalangan pesakit wanita berbangsa India yang melahirkan anak melalui bantuan alat vakum dan forsep dari 1 Januari 2015 sehingga 30 April 2021 di Hospital Tuanku Ja'afar, Seremban. Hanya kelahiran bayi hidup tunggal >35 minggu kehamilan dengan bayi normal yang dimasukkan ke dalam kajian ini. Analisa statistik dilakukan menggunakan SPSS versi 26 dan ujian Pearson chi-square test, Fisher Exact test dan Independent t-test digunakan bagi menentukan kepentingan statistik. Kajian ini telah diluluskan oleh Jawatankuasa Etika Penyelidikan USM (JEPeM-USM) dengan protokod kod USM/JEPeM/21040295 dan National Medical Research Registry (NMRR), Kementerian Kesihatan Malaysia, dengan protocol kod NMRR-21-566-59242.

Hasil Kajian: Kadar kelahiran secara vakum dan forsep dalam kajian ini adalah sebanyak 4.1%. Dalam kajian kami, sebanyak 269 pesakit telah dianalisa, 233 (86.6%) secara vakum dan 36 (15.4%) secara forsep. Tidak terdapat perbezaan yang signifikan antara komplikasi terhadap ibu dan jenis kaedah kelahiran yang digunakan. Bagi komplikasi ke

atas bayi antara kumpulan kelahiran secara vakum atau forsep, tidak terdapat perbezaan yang signifikan dari segi skor Apgar, keperluan untuk kemasukan SCN atau NICU, resusitasi, atau kecederaan kepala bayi.

Kesimpulan: Kelahiran secara vakum digunakan lebih kerap daripada forsep disebabkan oleh kurang risiko luka pada saluran faraj ibu. Kesimpulannya, kedua-dua alat bantuan kelahiran vakum dan forsep adalah kaedah selamat yang digunakan di bawah pengendali terlatih. Dengan lebih banyak latihan yang diberikan kepada pengendali terlatih, ianya boleh membantu mengurangkan lagi kadar pembedahan caesarean yang berlaku.

1.6 ABSTRACT

ABSTRACT

Introduction: The term operative vaginal delivery refers to a delivery in which the operator used an instrument to facilitate the delivery of the fetus. The two methods used in operative vaginal delivery are vacuum and forceps. Both instruments used are associated with risks to the maternal and neonatal. The purpose of this study is to determine the prevalence, the indications of operative vaginal delivery, and the maternal and neonatal outcomes among Indian patients who delivered via operative vaginal delivery in Hospital Tuanku Ja'afar, Seremban, Negeri Sembilan.

Method: A retrospective study was conducted by reviewing 269 medical records among Indian women who delivered via operative vaginal delivery in Hospital Tuanku J'afar, Seremban from 1st January 2015 to 30th April 2021. Only singleton live birth delivery >35 weeks gestational age with normal fetus was included in the study. Statistical analysis was performed with SPSS Version 26. This study has been approved by the Research and Ethics Committee of the School of Medical Science, USM (JEPeM-USM), with assigned study protocol code USM/JEPeM/21040295, and the National Medical Research Registry (NMRR), Ministry of Health Malysia, with assigned study protocol code NMRR-21-566-59242.

Results: Operative vaginal deliveries rates in this study were 4.1%. A total of 269 participants were recruited for this study, 233 (86.6%) were vacuum and 36 (15.4%) were forceps assisted deliveries. The indications for operative vaginal deliveries was similar between the two study groups and fetal distress was the most common indication for both

ways of operative vaginal delivery (93.1% and 94.4%, respectively). There was no significant difference in maternal outcomes between the two-study groups. Post-partum haemorrhage and lateral vaginal wall tear did not differ significantly between vacuum and forceps delivery. There were no significant differences between vacuum and forceps-assisted delivery with regards to Apgar score <5 in 1 minute (9.4% versus 8.3%, p=0.613), Apgar score <7 in 5 minutes (6.4% versus 2.8%, p=0.409). There was no significant difference between vacuum and forceps-assisted delivery group with regards to admission to NICU or SCN, with p-value=0.347. In vacuum-assisted delivery group, 46 babies (19.7%) required intubation and in forceps-assisted delivery group 5 babies (13.9%) required intubation. In vacuum-assisted delivery group, 34 babies (14.6%) sustained cephalhematoma and in forceps-assisted delivery group 1 baby (2.8%) sustained cephalhematoma.

Conclusion: Results of the present study showed vacuum was used more frequently than forceps. Both instruments are safe methods used in operative vaginal delivery in the hand of a trained operator. Enhanced training of obstetricians in instrumental delivery may aid in further reducing the prevailing caesarean section rates.

Key words: operative vaginal delivery, vacuum, forceps, maternal and neonatal outcomes.

CHAPTER 2

INTRODUCTION

2.0 INTRODUCTION

Operative vaginal delivery has been described since the Middle Ages. During this time, however, labour would be sustained over several days and intrapartum death almost unavoidable. In these dire circumstances, intervention involving the use of surgical instruments or even kitchen utensils would serve purely as an attempt to prevent maternal mortality. The establishment of forceps-assisted delivery as a means of preventing both maternal and neonatal morbidity was initiated in the 16th century by the Chamberlain family. It was later developed over several centuries by leading obstetricians of the time including Simpson, Barnes and Keilland [1].

Meanwhile, vacuum extraction was first described in 1705 by Dr James Yonge, an Englishman. However, it did not gain widespread use until 1950s, when in was popularized by the Swedish obstetricians Dr Tage Malmstrom. By the 1970s, the vacuum extractor had almost entirely replaced forceps as assisted vaginal deliveries in most Northern European countries.

The term operative vaginal delivery refers to a delivery in which the operator uses an instrument to facilitate the delivery of the fetus. It is also known as instrumental vaginal delivery or assisted vaginal delivery [2]. The two methods used in operative vaginal delivery are vacuum and forceps. Both instruments used require skilled and experienced obstetrician [3]. For many obstetricians these two instruments are interchangeable, while others are more comfortable with one or the other [4]. The choice between these two instruments is based on availability of equipment and resources and training exposure [5].

There are several types of vacuums available, namely metal cup, silicon cup and plastic Kiwi cup. However, in HTJS the metal cup is widely used here. For forceps, over 700 different types of obstetrical forceps so far in history [6]. Myerscough delineates the basic dissimilarity in the mechanics of head extraction by forceps and vacuum extractor [7]. The author explains that with forceps, pulling force is applied at the base of skull, while with vacuum; extraction of the head is affected with scalp traction by suction.

There is no absolute indication for operative vaginal delivery, and evaluation of each case should be done on an individual basis. Pre-requisites must be fulfilled prior to proceeding with operative vaginal delivery such as the fetal head is engaged, cervix is fully dilated, the membranes are ruptured, and the fetal head position identified.

Operative vaginal delivery is indicated as either for fetal indications, mainly fetal distress to prevent hypoxic brain damage, or maternal indications including poor maternal effort, prolonged second stage of labour, maternal conditions that require shortening of second stage of labour, e.g., cardiac diseases (Green Top Guideline No. 26).

Forceps and vacuum have been compared in many studies, both are associated with increased risk of maternal and neonatal injury when compared to normal spontaneous vaginal deliveries. Poor maternal and neonatal outcomes have also been reported after the sequential use of vacuum or forceps for assisted vaginal delivery.

According to WHO, operative vaginal delivery is one of the six critical functions of basic emergency care [9]. Therefore, it is very important to realise the fact that operative vaginal delivery procedure should be made available and accessible everywhere and all obstetricians are well trained to perform the procedure. In this present day, when there is a universal concern regarding the alarming rise of caesarean section rates, a better understanding of this instrument will help the patients as well as the obstetrician.

For the past 30 years, the use of operative vaginal delivery has decreased significantly, and because of that, the rate of caesarean section delivery increased. An update bulletin from ACOG (2015) reinforces the use of operative vaginal delivery to avoid caesarean delivery and improve outcome for both mothers and babies. With the help of forceps and vacuum extraction, vaginal delivery can often be achieved faster than caesarean delivery. Therefore, it can shorten fetal exposure to additional labour and decrease the effect of intrapartum insult on the fetus that is showing sign of fetal compromise.

Furthermore, this study is aimed to determine the indications, and maternal and neonatal outcomes following forceps and vacuum applications in operative vaginal deliveries among Indian patient, in our center, which is a tertiary health center, considering literature information.

2.1 LITERATURE REVIEW

A retrospective observational study done by Berna *et al*, 2017: comparison of maternal and neonatal outcomes of operative vaginal deliveries, vacuum vs forceps [10]. A total of 105 operative vaginal deliveries were performed. The results showed the incidence of operative vaginal delivery was 1.4% of all deliveries. Most of the patients were primigravida. The most common indication was fetal distress in the vacuum group and prolonged second stage of labour in forceps group. The risk and benefits of both instruments must be individualized, and operative vaginal deliveries should be performed only if considered a safe alternative. The choice of instrument depends on the operative's skills and training.

Recent retrospective cohort study by Nihal *et al*, 2020 (Maternal and Neonatal Outcomes of operative vaginal deliveries) found out that 3.8% deliveries were operative vaginal deliveries [11]. The most common instrument used was the plastic Kiwi cup vacuum device. No significant difference was found between the type of tears and instrument used except with perineal tears ($p=0.003$) which was seen more in the vacuum group particularly Kiwi cup. Operative vaginal delivery is an alternative idea to caesarean section with less maternal and neonatal complications if done by a well-trained obstetrician.

A retrospective study done by Shabnam TS *et al,* 2011: Short term maternal and neonatal outcomes in operative vaginal deliveries in singleton term pregnancies [12]. Sixty consecutive cases who underwent forceps delivery were compared with sixty consecutive

cases who were delivered by vacuum extractor. The two groups vacuum assisted delivery versus forceps delivery did not vary significantly with respect to maternal age, parity, weight, height, and indication for application of instrument. Neonatal outcome in terms of birth weight, gestational age and Apgar score was similar between the two groups. Maternal birth canal trauma in the form of second- and third-degree perineal tear was significantly more common with forceps delivery (11.67% vs 3.33%), p=0.032 vs p=0.027 respectively) [12]. There was significantly increased incidence of cephalhematoma and neonatal jaundice with the use of vacuum extractor (20% vs 5%, p=0.013 vs 3.33% respectively). No serious maternal and fetal morbidity was seen in both groups.

Another study conducted by Zenebe H *et al*, 2018: Prevalence and Outcome of Operative Vaginal Delivery, a cross sectional study among 242 mothers who gave birth by operative vaginal delivery [13]. The commonest indication was found to be non-reassuring fetal heart rate pattern (56.2%) followed by prolonged second stage of labour (24%).

A prospective randomized study done by Shekhar S *et al*, 2012: involving 100 women who requiring assisted vaginal delivery in the second stage of labour and they were randomized to deliver by forceps or vacuum extraction [1]. The results showed that severe maternal trauma (3rd degree perineal tear, cervical tear, paraurethral tear) was seen in 40% of forceps deliveries compared with 10% of vacuum deliveries (p<0.001). Vacuum delivery, however, appears to predispose to an increase in neonatal jaundice and incidence of cephalhematoma[1] (Shekhar S *et al*, 2012).

An observational prospective cohort study done Shameel F *et al*, 2016: Instrumental vaginal deliveries at tertiary centre [15]. The incidence of instrumental vaginal delivery was 2.8% of all deliveries, in 70.56% patients, it was indicated because of prolonged second stage of labour. Out of all newborns, 82 newborn babies had birth asphyxia for which NICU admission was required.

According to Bailey *et al.* 2005, the World Health Organisation considers operative vaginal delivery to be critical part of basic emergency obstetric care [16]. Current trends show that the caesarean delivery rate has increased over the past decade (30.3% in the USA and 21.3% in England in 2001), while the operative vaginal delivery rate has decreased overall [17].

The rate of operative vaginal delivery in the US dropped from 9.01% to 3.3% in 2013 [17]. In England, despite a progressive increase in caesarean deliveries over the past 20 years, reaching 23% of births in 2004, the instrumental delivery rate has remained stable at 10-11% of all births. (NHS maternity Statistics, England 2004-2005).

Although the rate of operative vaginal deliveries is dropping, vacuum has emerged as the most popular delivery instrument in the US. Vacuum deliveries comprised 4.1% of all live births in 2004, whereas forceps deliveries dropped dramatically from 5.5% in 1989 to 1.1% in 2004 [18].

Evidence suggests that forceps are associated with less failure than vacuum extraction. A study by Murphy DJ *et al*. 2001 stated that caesarean section was more likely to be done after attempted vacuum delivery than after attempted delivery by forceps [19]. Delivery by forceps is also quicker than vacuum extraction, which may be of critical importance with fetal distress.

2.2 ROYAL COLLEGE OF OBSTETRICIANS AND GYANECOLOGISTS (RCOG) RECOMMENDATIONS FOR THE OPERATIVE VAGINAL DELIVERY

The RCOG Green-top Guideline 'Operative Vaginal Delivery; Green-top Guideline No. 26 concerning the up-to-date information on the use of forceps and vacuum extractor so that the obstetricians are competent in the use of both instruments [8]. It was published in January 2011 and is currently in use at the time this thesis was written. All clinical recommendations from the RCOG Green-top Guideline No. 26 have been incorporated into the Hospital Tuanku Ja'afar, Seremban for the management of operative vaginal delivery. Therefore, throughout this thesis written, definitions for operative vaginal delivery, classification of operative vaginal delivery, indications of operative vaginal delivery are as per the RCOG Green-top Guideline 'Operative Vaginal Delivery; Green-top Guideline No. 26.

2.2.1 Classification of operative vaginal delivery

To enable bench marking, audit and comparison between studies, a standard definition of the types of operative vaginal delivery should be used. The American College of Obstetricians and Gynecologists criteria are adapted and define the delivery by station and position [20].

The classification of operative vaginal deliveries by ACOG (2000):

1) Outlet

   a. Fetal scalp visible without separating the labia

   b. Fetal skull has reached the pelvic floor

   c. Sagittal suture is in the anterior-posterior diameter or right or left occiput anterior or posterior position (rotation does not exceed 45^{o})

   d. Fetal is at or on perineum

2) Low

   a. The leading point of the skull (not caput) is at station plus 2 cm or more and not on the pelvic floor

   b. Two subdivisions:

      i. Rotation of 45^{o} or less from the occipito-anterior position

      ii. Rotation of more than 45^{o} including the occipito-posterior position

3) Mid

a. Fetal head is no more than $1/5^{th}$ palpable per abdomen

b. The leading point of the skull is above the station plus 2 cm but not above the ischial spines

c. Two subdivisions:

i. Rotation of 45^{o} or less from the occipito-anterior position

ii. Rotation of more than 45^{o} including the occipito-posterior position

4) High

a. Not included in the classification as operative vaginal delivery is not recommended in this situation where the head is $2/5^{th}$ or more palpable abdominally and the presenting part is above the level of the ischial spines.

2.2.2 Indications for operative vaginal delivery

Operative intervention is used to shorten the second stage of labour. It may be indicated for conditions of the fetus or the mother. A retrospective cohort study of 15,759 nulliparous women demonstrated that maternal morbidity increased significantly after 3 hours of second stage and further increased after 4 hours. (Cheung TW *et al*. 2001).

Indications for operative vaginal deliveries

1) Fetal indication

- presumed fetal compromised

2) Maternal indications:

- to shorten and reduce the effects of the second stage of labour on medical conditions (e.g., cardiac disease, hypertensive crisis and myasthenia gravis, spinal cord injury patients at risk of autonomic dysreflexia, proliferative retinopathy)

3) Inadequate progress

- Nulliparous women: lack of continuing progress for 3 hours (total of active and passive second-stage labour) with regional anesthesia, or 2 hours without regional anesthesia
- Multiparous women: lack of continuing progress for 2 hours (total of active and passive second-stage labour) with regional anesthesia, or 1 hour without regional anesthesia
- Maternal fatigue/exhaustion

There are few contraindications for operative vaginal deliveries;

- Cervix is not fully dilated
- Signs of cephalo-pelvic disproportionate:
    i. significant caput and moulding
    ii. high station
    iii. narrow pelvic outlet
- No descent with maternal effort
- Indeterminate fetal position
- Face presentation
- Previous OASIS – relative contraindication
- Fetal causes (bleeding disorders)
- Unskilled professional

There are few indications specific to forceps delivery or another word forceps delivery is usually superior to vacuum extraction: - (Patel RR *et al*. 2004).

- Delivery of fetal head at assisted breech delivery (singleton or twin)
- Assisted delivery of preterm infant (<34 weeks gestation)
- Controlled delivery of head at caesarean section
- Assisted delivery with a face presentation
- Assisted delivery of fetus with suspected coagulopathy or thrombocytopenia

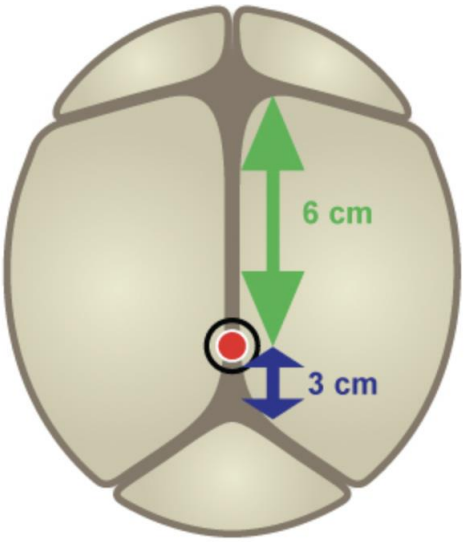
- Instrumental delivery for maternal medical conditions that preclude pushing
- Instrumental delivery under general delivery/intubated mother
- Cord prolapsed in the second stage of labour

Advanced Life Support in Obstetrics (ALSO) programme promoted the safe technique for instrumental delivery by the acronym ABCDEFGHIJ. (Danos JR *et al*. 2004).

A	Ask for help, address the women, palpate the abdomen, ensure anesthesia is adequate
B	Bladder is empty
C	Cervix completely dilated
D	Determine position
E	Equipment

For vacuum delivery

F	Flexion point – apply the cup over the sagittal suture and in relation to the posterior fontanelle. The flexion point is located on the sagittal suture 3 cm in front of the posterior fontanelle.



The flexion point is the key landmark in vacuum delivery. If the cup is not applied over this point, deflection of the head and cup detachment is more likely to occur.

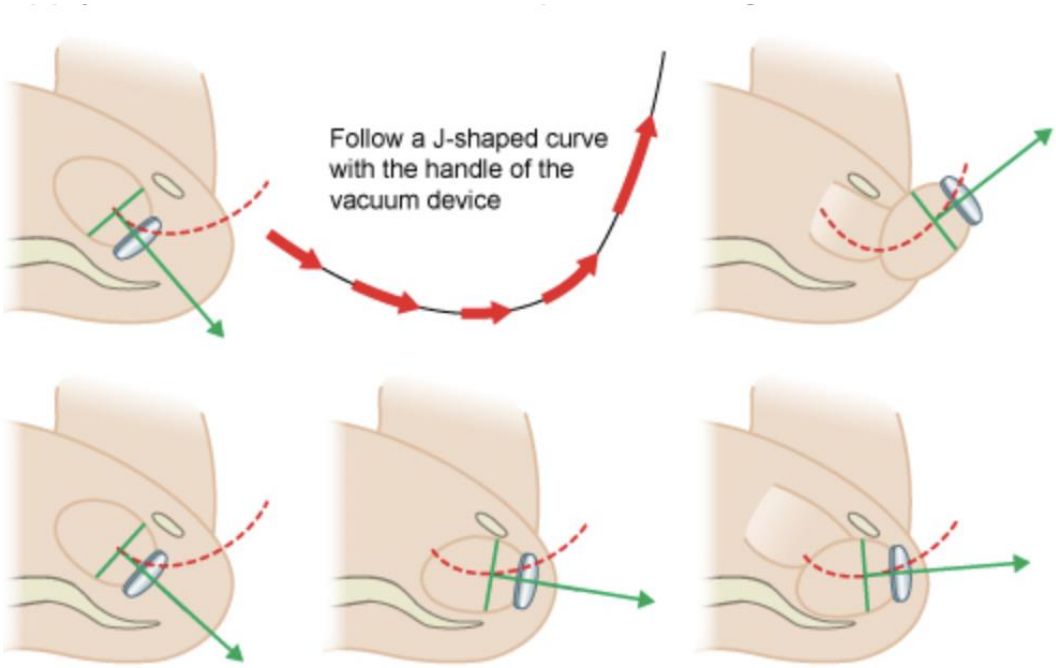
The sagittal suture should be centered under the vacuum. The vacuum should be checked to ensure there is no maternal tissue entrapped within the vacuum cup.

G Gentle, steady traction applied at right angles to the cup, the axis of traction following the pelvic curve

H Halt the procedure if there has been no descend with 3 consecutive pulls or the cup detaches 3 times or 15 minutes has elapsed since application of the cup

I Incision – routine episiotomy is not necessary

J Remove the cup when the jaw is visible



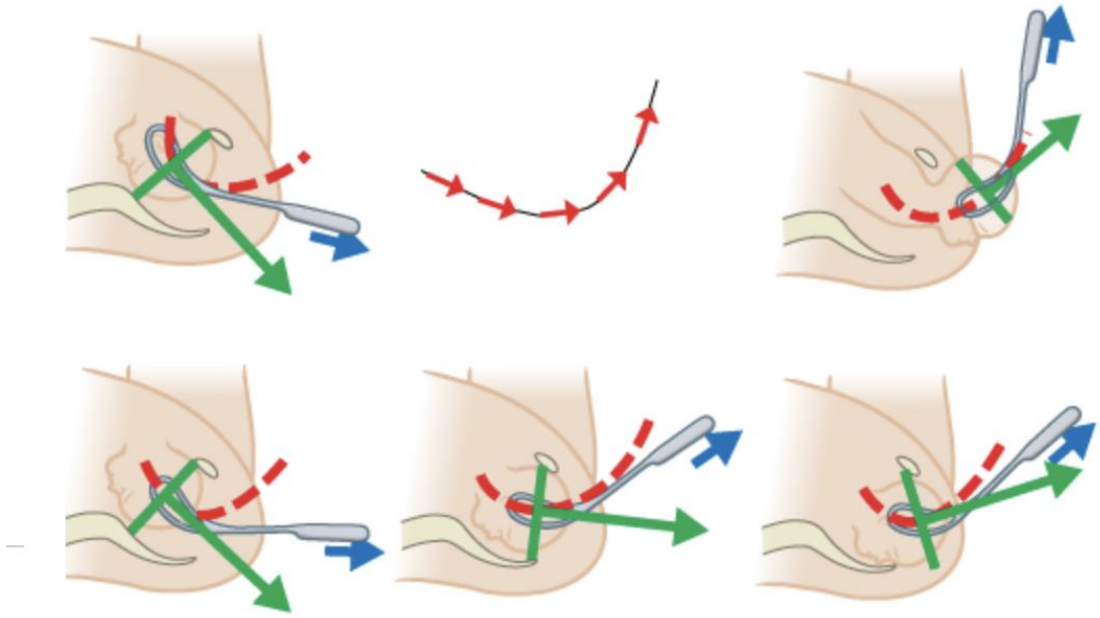
For forceps delivery:

A – E As above

F The forceps blades are applied and checked. The posterior fontanelle should be located midway between the sides of the blades, with the lambdoid sutures equidistance from the blades and one fingerbreadth above the plane of the shank. A distance greater than this indicates that the head is extended, if the distance is less than one fingerbreadth, this indicates the head is over-flexed.

G Gentle traction, Ease the grip in between contraction, to reduce compression of baby's head

H Halt, abandoned the procedure if there is no descend with 3 contractions or pull or if 15 minutes have elapsed



The attempt at instrumental delivery should be abandoned if (Edozien LC 2007):

1) There is difficulty in applying the instrument
2) There is no descent with each pull
3) Delivery is not imminent following 3 pulls of a correctly applied instrument
4) A reasonable time (15-20 minutes, depending on the local protocol) has elapsed

and the baby has not been delivered.

2.3 STUDY JUSTIFICATION AND BENEFIT OF STUDY

Operative vaginal delivery is an ideal alternative to caesarean section with less maternal and neonatal complications in women who cannot deliver spontaneously, if done by a well-trained obstetrician. Risks and benefits of both instruments must be individualized, and operative vaginal deliveries should be performed only if considered a safe alternative. This study is also beneficial to collect local data regarding maternal and neonatal outcome of operative vaginal delivery among Indian patients in HTJS. Many operative vaginal deliveries were performed to facilitate childbirth and to reduce the rate of caesarean section and its complications. It also serves as an audit for operative vaginal delivery performed that complicated with maternal and neonatal morbidity and worse, mortality. The study is also beneficial to improve knowledge and skills of medical practitioner regarding operative vaginal delivery and therefore to minimise its complication.

In the study site (HTJS), the Indian population is common, thus it is a good opportunity to study in this ethnic group of patients. Previously no other study has been done involving Indian patients in Malaysia from the literature. The results of this study can be used as a reference for future meta-analysis purpose. Thus, it is a good opportunity with good sample size. There was one study has been done regarding a retrospective review of operative vaginal delivery in HUSM. Hence, after discussion at department level, the suggestion is to do the study population among Indian patients who delivered via operative vaginal delivery in HTJS.

CHAPTER 3

OBJECTIVES

3.0 OBJECTIVES

3.1 General Objective

To determine the maternal and fetal outcome among Indian patients who delivered via operative vaginal delivery in Hospital Tuanku Ja'afar Seremban (HTJS), Negeri Sembilan.

3.2 Specific Objectives

3.2.1 To determine the prevalence of operative vaginal deliveries in HTJS.

3.2.2 To determine the indications of the operative vaginal delivery among Indian patient in HTJS.

3.2.3 To determine the maternal outcomes (postpartum hemorrhage and lateral vaginal tear) among Indian patients who delivered via operative vaginal delivery in HTJS.

3.2.4 To determine the neonatal outcomes (cephalhematoma and requirement admission to NICU) among Indian patients who delivered via operative vaginal delivery in HTJS.

CHAPTER 4

METHODOLOGY

4.0 METHODOLOGY

4.1 Study setting

The study was conducted in Hospital Tuanku Ja'afar Seremban, Negeri Sembilan, Malaysia. It is a tertiary hospital and serves a multidisciplinary department. The maternity labour ward has a delivery rate of 9,514 per annum (Statistic Hospital Tuanku Ja'afar Seremban, 2020).

4.2 Study design

A retrospective review of 269 Indian patients who were delivered via operative vaginal delivery in Hospital Tuanku Ja'afar Seremban, Negeri Sembilan from 1st January 2015 to 30th April 2021.

4.3 Study population

All Indian patients who were delivered via operative vaginal delivery in Hospital Tuanku Ja'afar Seremban, Negeri Sembilan, who meet the following inclusion criteria and lack of the following exclusion criteria were enrolled in this study.

Inclusion criteria

All Indian patients who were delivered via operative vaginal delivery in HTJS, within the period of 1st January 2015 till 30th April 2021.

Singleton pregnancy

>35 weeks period of gestation

Normal fetus

Fulfilled criteria for operative vaginal delivery according to hospital protocol

Exclusion criteria

Incomplete data

Used double instrumentation

4.4 Sample size determination

The sample size was calculated by using the Calculator by Dr Wan Nor Arifin by comparing 2 proportions [24].

For maternal outcomes, I compared the proportions of postpartum haemorrhage and lateral vaginal wall tear among Indian patients who delivered via operative vaginal delivery.

For neonatal outcomes, I compared the proportions of cephalhematoma and requirement of admission to NICU among Indian patients who delivered via operative vaginal delivery in is sample size in each group

α is 0.05 power is 80%

p0 is the expected proportions of study outcome in the control group (instrumental delivery)

p1 is the expected proportions of study outcome in the case group (normal delivery)

4.4.1 Sample size estimation for the specific objective number (3.2.3)

1. Association of postpartum hemorrhage as maternal outcomes for instrumental deliveries among Indian patients.

P0 value: proportion of postpartum haemorrhage among those with instrumental delivery from literature is 3% (0.03)

P1 value: expected proportion of postpartum haemorrhage among those with normal delivery is 13% (0.13) [Berna AC et al, 2017]

Therefore, the sample size is 115.

2. Association of lateral vaginal wall tear as maternal outcomes for instrumental deliveries among Indian patients.

P0 value: proportion of lateral vaginal wall tear among those with instrumental delivery from literature is 14% (0.14)