

A prospective study on reporting of critical events of low risk postnatal women in the postnatal period who delivered in a teaching hospital in South- India through telephonic conversation- an observational study



A dissertation submitted in partial fulfilment of rules and regulations for the MS Branch II (Obstetrics and Gynaecology) examination of the Tamil Nadu Dr. M.G.R. Medical university, Chennai to be held in May 2020.

CERTIFICATE

This is to certify that this dissertation entitled “**A prospective study on reporting of critical events of low risk postnatal women in the postnatal period who delivered in a teaching hospital in South India through telephonic conversation- an observational study**” is bonafide work done by Dr. Parisuddharao Koduri in partial fulfilment of the requirement of MS Branch II (Obstetrics and Gynaecology) examination of the Tamil Nadu Dr. M.G.R. Medical university, Chennai to be held in May 2020.

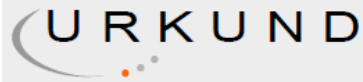
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Guide

Dr Reeta Vijayaselvi

Professor

Obstetrics and Gynaecology- Unit- 4

Christian Medical college, Vellore.

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ABSTRACT

Primary Objective: To assess the prevalence of maternal and neonatal complications (reporting of critical events) in the low risk postnatal women in puerperal period

Methods:

This is a prospective observational study which was done in the department of Obstetrics and Gynecology at Christian Medical College Vellore. Low risk postnatal mother and baby pairs up to postnatal day 4 at the time of discharge were invited to participate for study. The patients were contacted at 2nd and 4th week of postpartum by telephonic contact and advised patients to call whenever mother and baby has problem. The prevalence of maternal and neonatal concerns was assessed at the end of the study by its frequency. Comparison of quantitative variables were done by mean and median

RESULTS AND CONCLUSIONS

The incidence of maternal events at 2nd week vs 4th week of postpartum are, wound related events 57 vs 14, breast related 23 vs 14, secondary PPH 7 vs 1, UTI 11 vs 4. The major events for mothers from our study are wound related concerns 26.19%, breast feeding related 13.65%, loose stools and constipation 7.40%, fever 6.27%, Urinary tract infection 5.53%, secondary postpartum hemorrhage 2.95% and miscellaneous 5.13%. The incidence of maternal events from the 2nd week to 4th week of postpartum reduced from 131 to 54 events.

Babies had a total of 51 critical events by 2nd week. Out of which 25% events are for common cold, 23% events for excessive crying, 13% for umbilical discharge, 11% for loose stools and 25% events miscellaneous. Babies had a total of 22 events from the beginning of 3rd week to 4th week of postpartum. Most of the events for common cold, loose stools, excessive crying and miscellaneous. The total events for babies at the end of 2nd week is 51 and at the end of 4th week is 22. The incidence has reduced to more than half by the end of 4th week postpartum. The major concerns for babies from our study are common cold 6.64%, excessive crying 5.16%, discharge from the umbilicus 2.95%, loose stools 2.95%, and miscellaneous 6.21%.

Bivariate analysis showed, there is no significant relation between sociodemographic variables and critical events for mothers as well as for babies. Most of the critical events are happening in the second week for mothers as well as for babies. So, the mother-baby pair can have postnatal visit at 2nd week of postpartum in addition to visit at 6th week of postpartum. Follow up of the critical events will tell the magnitude of critical events.

INTRODUCTION

Postnatally, the mother will be recovering physiologically from delivery. Some mothers can have problems like fever with foul smelling vaginal discharge, breast feeding issues, episiotomy wound pain, infection, issues related to personal hygiene, nutrition and issues regarding resuming sexual life. They may not seek medical help during postnatal period for minor illness. Though continuous postnatal medical and supportive care during postnatal period is the best for mother and the neonate, it is not provided adequately because of lack of medical personnel, lack of transport facilities and financial support.

Telemedicine holds the promise of improving access to health care, especially in areas where there are geographical barriers and of reducing costs. Phone based technology has potential to improve the healthcare services in reproductive age women in developing countries. Telephonic support in developed countries showed improved breast feeding rates, depression states, contraception usage, improvement in quality of life and increased satisfactory rates with the hospital follow up.

Our study will contribute to the knowledge of prevalence of the postnatal concerns in the 6 weeks postnatal period and assess whether the telephone can be used as an alternative to physical visit to the hospital for addressing the concerns of mother and the neonate during the postnatal period. If this proves effective, this can be adopted as a model to provide continued postnatal care facility.

AIMS AND OBJECTIVES

Aim: To assess the prevalence of maternal and neonatal complications (reporting of critical events) in the low risk postnatal women in puerperal period.

Objectives

1. To know the prevalence of the need for reporting of critical events in the postnatal women and her baby after discharge.
2. To assess the relation between the reporting of critical events and socio demographic and clinical variables.
3. To assess the satisfactory level of the postnatal women following the telephonic conversation of their reported critical events.

Literature review

During the postnatal period, most of the physiological changes of pregnancy will be normalized. Though major maternal and neonatal morbidities are less common in the low risk postnatal women, issues regarding breastfeeding, wound healing, emotional wellbeing and neonatal care still bother the woman and the family

Normal puerperium

According to the various authors the period between 4 to 6 weeks from the time of placental delivery is called puerperal period. The first few hours after delivery are referred to as immediate postnatal period. 25-50% of patients can have postpartum chills which may last for 1hr.

Anatomical and physiological changes

Uterus

The uterus will be well contracting soon after the expulsion of the placenta. The fundus will be at the level or below level of the umbilicus. Involution of uterus takes place during puerperal period. The fundus lies in-between the umbilicus and the symphysis-pubis after 1 week of delivery. 2 weeks after the delivery uterus won't be

palpable. Uterus will become the pelvic organ 2 weeks after the delivery. Soon after the delivery the uterus will be 1000gms and after 4 weeks of delivery weight will be 100gms. Lower segment will contract and will become isthmus.

Cervix

The cervix which was dilated to 10cm at the time of delivery will contract gradually and thickens. The rounded external os in the nulliparous women will become transverse slit in multipara. By the end of 6 weeks the os will become to its pre-pregnant state with the transverse slit.

Endometrial changes

1-2 days after the delivery the decidua differentiates into two layers. The outer layer becomes necrotic, sloughs, and expelled with the lochia. The basal layer or deeper layer of decidua will remain for the source of new endometrium. The placental site and rest of the endometrium is infiltrated with granulocytes and lymphocytes. After 10days of delivery the leukocytic infiltration will decrease.

Lochia

The discharge from the uterus in the postpartum period is known as lochia. The bloody discharge after 4-5 days of delivery is called Lochia rubra. It consists of blood and sloughed decidua. During the next 2-3 weeks the discharge is pale and thinner and little

blood stained is called Lochia serosa. The above both will have fishy odor. Following this yellowish-white discharge referred as Lochia alba and this will persist for 6-8 weeks.

Vagina

The contraction of the vagina will start from 2-3 days after the delivery. The vaginal rugae will start appearing from 3rd week after the delivery. But not very prominent as pre-pregnant state. The vaginal orifice will be lax due to stretching of pelvic floor muscles and tears of pelvic floor.

Abdominal wall

The abdominal wall is flabby, and muscles are lax in the immediate postnatal period. The muscles regain their tone over a period. Divarication of recti will persist. The rupture of the elastic fibers of the skin results in stria gravidarum, which will be white lines and they are permanent.

Ovarian function and ovulation

In lactating women, prolactin levels remain elevated and estrogen levels decreased till about 6 weeks. In non-lactating women the levels normalize after 2-3 weeks. During lactating period, the follicular stimulating hormone levels are normal, but the ovaries will be unresponsive for the stimulation. These changes are the basis for ovulation suppression and amenorrhea. In non-lactating women ovulation resume after 75days of delivery, and menstruation may resume by 8-12 weeks. In lactating women, the ovulation may resume by 6 months, but amenorrhea will continue for 1-2 years depending on the duration of breast feeding.

Urinary tract

The dilatation of the renal pelvis and ureter, in renal plasma flow, and glomerular filtration rate return to normal by 6-8 weeks postpartum. Immediately following delivery there is edema and submucosal hemorrhage in the bladder with associated increase in bladder capacity and mild reduction in bladder sensation.(2)

Because of these changes' urine stasis in the bladder, incomplete voiding and bladder distension can occur. Epidural analgesia and reflex spasm of urethra due to pain at episiotomy site and para-Urethral tears can worsen these. Urinary incontinence can occur due to prolonged labour and instrumental delivery, due to stretching and damage to the pelvic floor muscles.

Lactation and breast feeding

Prolactin will be under the inhibitory effect of dopamine and it will be removed by the sound of baby's first cry. Breast feeding should begin within an hour after the delivery. Oxytocin will get stored in posterior pituitary gland. It acts on myoepithelial cells and lactiferous ducts to eject the milk. Prolactin is the most important hormone for continued lactation.

Endocrinology of lactation

Progesterone, estrogen, placental lactogen, prolactin, cortisol and insulin appears to act in concert to stimulate the growth and development of the milk secreting apparatus(3).

With delivery, the maternal serum levels of progesterone and estrogen decline abruptly. This fall in progesterone levels, remove the inhibitory influence of progesterone on alpha-lactalbumin production and stimulates lactose synthase to increase milk lactose. Progesterone withdrawal also allows prolactin to act unopposed in its stimulation of alpha-lactalbumin production. Activation of calcium-sensing receptors in mammary epithelial cells downregulate parathyroid hormone-related protein and increases calcium transport into milk. Serotonin is also produced in mammary epithelial cells and has a role in maintaining milk production

Abnormal puerperium:

First 6 weeks after delivery is very crucial for mother and the neonate. During this period all the physiological changes of pregnant women to be normalize to prepregnant state. There is a chance that puerperium can be abnormal also.

Causes for Abnormal puerperium

- **Secondary PPH**
- **Puerperal pyrexia**
- **Mastitis and feeding problems**
- **Wound infection**
- **Thromboembolism, DVT**
- **Septic pelvic thrombophlebitis**
- **Neuropathy**
- **Musculoskeletal injuries**
- **Mental health problems**
- **Neonatal problems**

1.Secondary Postpartum hemorrhage

Any increased bleeding per vaginum from 24hrs of delivery within 6 weeks period is called secondary (Delayed) postpartum hemorrhage, which requires active management. The incidence of secondary postpartum hemorrhage according to various authors will be ranging from 0.5-2%(4). Clinically worrisome hemorrhage can occur within the period of 1 to 2 weeks after delivery among 1% of population.

Causes of secondary postpartum hemorrhage are mostly subinvolution because of retained placental tissue, endometritis, pseudo aneurysms of uterine artery, physiological resumption of menses.(5)

Secondary postpartum hemorrhage can occur occasionally due to retained bits of placenta, later it will undergo necrosis and degeneration and it will become placental polyp. When polyp detaches from the endometrial base it will cause the severe hemorrhage. Rarely secondary postpartum hemorrhage is caused by von Willebrand's disease also (6). A retrospective study done on 16 patients with unrecognized von Willebrand's disease, the incidence of secondary postpartum hemorrhage among them was 31% (7). Very rarely the rupture of uterine artery aneurysm also can have secondary postpartum hemorrhage.(8)

Detailed obstetrical history, mode of delivery and genital tract injuries during the time of the delivery, history of bleeding disorders and thorough clinical examination will help in Clinching the diagnosis. Imaging like Ultrasound abdomen will help in diagnosing retained products in the endometrial cavity and sometimes it will be helpful to suspect Arterio-Venous malformations.

Treatment

Treatment will be different for each cause. For subinvolution, oxytocin and other uterotonics will helpful to make the uterus contract and to counteract the bleeding. Antibiotic coverage will help in treating endomyometritis. Gentle suction and evacuation will be helpful for removal of retained placental bits and membranes. Uterine artery embolization is helpful in AV malformations. Appropriate treatment and multidisciplinary approach will be required for treating the bleeding disorders

2. Puerperal pyrexia

The temperature of 38. 0°C (100.4°F) or more than 38. 0°C 24hrs after the delivery is called puerperal pyrexia.

Various causes were attributed for puerperal pyrexia.

- a. Endometritis
- b. Urinary tract infection/ pyelonephritis
- c. Mastitis
- d. Abdominal wound infection
- e. Perineal infection.
- f. Respiratory tract infection

a. Endometritis

After the delivery of the placenta, the placental bed or decidua will be considered as the wound anywhere else in the body. Endometritis can manifest as puerperal sepsis. Puerperal sepsis is defined as infection of the genital tract after the delivery till 6 weeks postpartum. It was the major cause of increased maternal mortality in the past. It is markedly reduced due to improved maternal care during the delivery time, availability of effective antibiotics.

Microbial flora during labour: According to the various authors the normal bacterial flora in the vaginal tract are, (9)

1. Lactobacilli (60-70%)
2. Candida albicans (25%)
3. Escherichia coli
4. Staphylococcus albus and aureus
5. Anaerobic streptococci
6. Bacteroides
7. Streptococcus beta hemolyticus (rare)
8. Clostridium welchii (rare)

Predisposing factors during the Antepartum time:

Maternal malnutrition, lower socioeconomic status, maternal anemia, pre labour rupture of membranes, other conditions like GDM, chronic illness requiring steroids or immunosuppressive drugs and antepartum hemorrhage are predisposing factors in the antepartum period.

Factors during intrapartum and postpartum

Caesarean delivery itself is a single most important risk factor for the postpartum endometritis(10). The risk is doubled with emergency LSCS than a planned LSCS(5-15% vs 30-35%). (9). The other factors contributing are,

Multiple vaginal examinations during the labour

Prolonged rupture of membranes more than 18hours

Instrumental deliveries

Manual removal of placenta.

Etiology:

With the above risk factors the normal organisms of the vaginal tract will ascend, causes the infection of the placental bed. Endometritis is a polymicrobial infection. Placental site will be affected usually. There will foul smelling vaginal discharge due to sloughing of the decidua. The infection can spread to the other areas and can cause pelvic peritonitis, pelvic abscess, septic thrombophlebitis, septicemia and septic shock.

Diagnosis

The signs for the diagnosis of endometritis are fever more than 100.4°F, foul smelling vaginal discharge with uterine tenderness and sub involuted uterus.

Management

For mild endometritis broad spectrum oral antibiotics is enough. For moderate to severe endometritis, intravenous broad-spectrum antibiotics are required. 90% of women will respond within 48-72hrs after starting the intravenous therapy. If fever is not subsiding after giving higher antibiotics, careful search should be done to diagnose septic thrombophlebitis. Antibiotics can be stopped after 24hrs of afebrile period.

b. Urinary tract infection

Various risk factors were attributed for the causation of UTI during the postnatal period. The dilated urinary system during antenatal time will take 2-3 weeks to become prepregnant state.

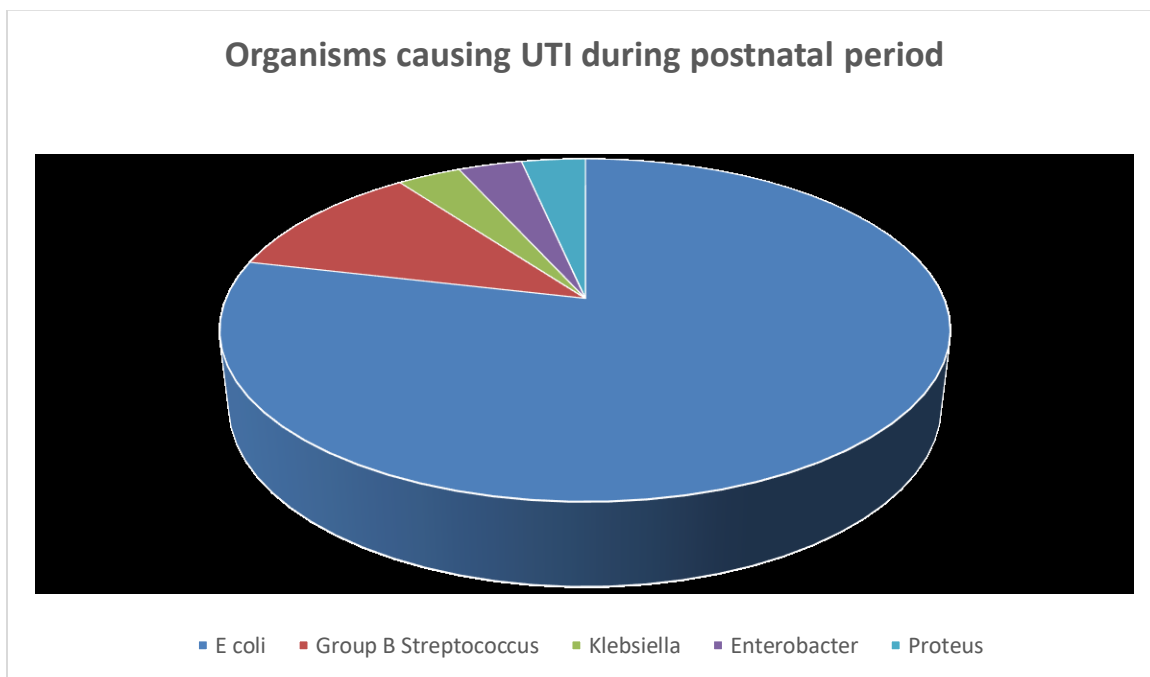
Risk factors for UTI during the postnatal period.

1. Urinary retention during the labour and immediate postpartum
2. Multiple catheterizations during intrapartum and postpartum
3. Improper catheterization

4. Bladder mucosal injury during labour.
5. Cesarean delivery itself is an individual risk factor for UTI(11)

The organisms responsible for UTI during postnatal period are Escherichia coli 70%, Group B streptococcus 10%. Other organisms like Klebsiella, Enterobacter, Proteus species will each attributed up to 3%(12)

Figure 1- Organisms causing Urinary Tract Infection.



The symptoms of lower UTI are dysuria, increased frequency and urgency. The upper UTI will be diagnosed with fever with chills, flank pain and renal angle tenderness. Urine routine and cultures should be performed to diagnose (12).

A cross sectional study done by Anjely et al in 2018 from Christian Medical College, Vellore, found that there was an association between premature pre labour rupture of membranes with mothers who had symptomatic UTI antenatally ($p= 0.001$). (13)

C. Mastitis and feeding problems

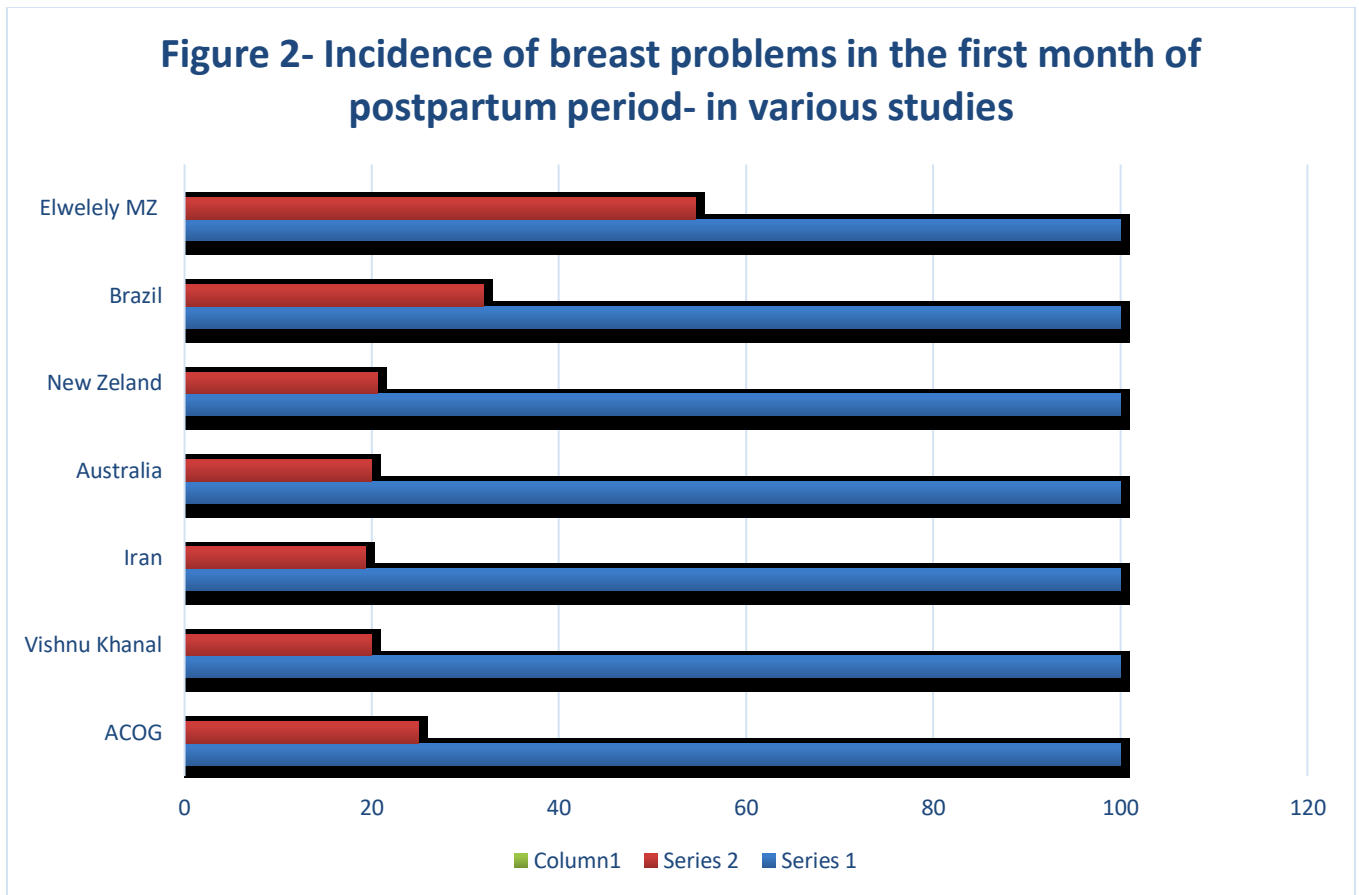
Parenchymal infection of the mammary gland is very rare during the antenatal period but goes up to incidence of 3% during the postnatal period. The incidence of acute mastitis varies according to the various authors.

According to American college of Obstetrics and Gynecology, postnatally around 25% women will face at least one episode of acute mastitis during 1st month of the nursing (14). A prospective cohort study done in Nepal by Vishnu Khanal et al, showed almost the incidence of mastitis was 20% during the first month of lactating period. (15)

A study reported from Iran showed the incidence of acute mastitis is 19.3% during the first 4 weeks period of postpartum(16).

Studies have reported from Australia and New Zealand showed the incidence of mastitis in the third and sixth month of postpartum was 20% and 20.6% respectively. Out of this 11% developed breast abscess (17). A cross sectional study done in Brazil in 2016 by Kamila Juliana da Silva Santos et al on Prevalence and factors associated with cracked nipples in the first month postpartum showed the prevalence of cracked nipples was 32 % in the first 30 days postpartum(18)

A study to investigate problem faced by newly breastfeeding mother by Elwelely MZ in 2018 in Egypt on 200 women in the postnatal period for 40 days showed ignorance about the importance of breastfeeding, lack of support and insufficient breast milk (23.0%, 21.5% and 15.0 respectively). More than half of the sample (54.6%) was exposed to nipple and breast problems such as; nipple soreness and cracking, breast engorgement and nipple size problems (51.5%, 39.0% and 34.0% respectively) and 76.0% were exposed to postpartum stress(19)



The common risk factors for mastitis are difficulty in breast feeding and cracked nipples, oral antibiotics usage during the breast feeding, improper usage of breast pumps, topical antifungals usage during the lactation and the separation of the mother and infant for more than 24 hrs.(20)

The most commonly isolated organism with mastitis and breast abscess is *Staphylococcus aureus* especially MRSA and it can cause Toxic Shock Syndrome. But very rarely Group A hemolytic streptococci can cause fatal and life-threatening breast abscess. Other causative organisms will be coagulase negative *Staphylococcus* and *Streptococcus viridans*.(21)

Management

Educating the mother about proper attachment and feeding the baby for treating a sore or cracked nipple. Mastitis should be treated with antibiotics before it becomes abscess. The infection usually resolves within 48hrs after starting the antibiotics. In general, it is advised to continue the feeding from the affected breast without any hesitancy. It was also observed that vigorous milk expression will reduce the abscess formation.(22)

The incidence of breast abscess is 0.1%. Any abscess in the body requires surgical drainage. Likewise, breast abscess needs surgical drainage under general anesthesia. Needle aspiration under ultrasound guidance is also done if the abscess is small.

Respiratory Tract Infection:

The morbidity and mortality rates due to respiratory infection are high during pregnancy than postnatal period. The Common postpartum respiratory problems are, upper respiratory tract infections (Bacterial/ Viral), postoperative aspiration pneumonia due to immobilization, community acquired pneumonia in immune compromised individuals are.

Influenza (Swine flu) infections are seasonal. Symptoms are fever, malaise, cough, sore throat, rhinorrhea, headache, myalgia, vomiting, and diarrhea. Mean duration of onset of symptoms from time of disease may be 2-6 days. Throat swab for culture, total white cell counts, chest radiograph may help in diagnosis. Antiviral drugs and symptomatic management are mainstay of treatment.

4. Wound infection

a. Abdominal wound infection:

Wound infection is the most common cause for the persistent fever in women treated for endometritis. Risk factors for cesarean wound infection include obesity, diabetes, anemia, malnutrition, low socio-economic state, patients on long term steroids and patients on immune suppressive drugs for long term. During the labour factors like chorioamnionitis is the single most common risk factor for causing postpartum abdominal wound infection(23)

Prolonged rupture of membranes more than 18hours, unscheduled cesarean operations, internal fetal monitors will increase the postnatal wound infection. Intra operatively inadequate hemostasis and hematoma formation also can predispose for wound infection. Long duration of surgery and exteriorization of uterus while suturing the hysterotomy wound can have the increased chances of wound infection (18). The incidence of cesarean wound infection varies according to the various studies ranging from 3.7% to 9.8%. (24)

A prospective study done in Norway stated that the incidence of caesarean wound infection rates are 1.8% during the hospital stay and 8.9% at postoperative 1 month (25).A case control study done by Bodelon et al in USA, reviewed 896 peripartum hysterectomies and stated that postpartum infection is a serious risk factor for peripartum hysterectomy.(26)

Caesarean wound dehiscence is also a serious complication which needs emergency fascia closure. Maternal obesity is the one of the most common risk factors for wound dehiscence. The incidence of wound dehiscence according to the various authors approximately 1 in 300 cesarean deliveries.(27)

B. Perineal wound infection

Episiotomy wound infections are very less now a days due to less performance of episiotomies comparatively in the past

The incidence of episiotomy infection was only 10 in 20,000 deliveries according to Owen and Hauth. The episiotomy dehiscence rate was only 0.5% in parkland hospital USA by Ramin and his colleagues (28). Infection of the episiotomy wound leads to wound dehiscence. Other rare risk factors are coagulation disorders, smoking and Human papilloma viral infection (28). Risk factors like instrumental deliveries will carry highest risk for wound infection and dehiscence.(29)

A prospective observational study done in Denmark among 600 vaginal deliveries showed, performing episiotomy and maternal severe obesity are the risk factors for episiotomy wound infection and wound dehiscence (30).

A retrospective cohort study done by Beena et al from Cristian Medical College, Vellore on postpartum wound dehiscence and its associative factors. They had evaluated almost 14,000 deliveries, and they found that wound dehiscence and infection were associated with induction of labour, primigravidae, instrumental deliveries, and Meconium stained amniotic fluid .(31)

Local pain and swelling, redness, dysuria with or without urinary retention and purulent discharge from wound site are some of the symptoms and signs of infection.

Treatment of infected wounds

Any wound in the body will be managed by the following steps with the current practice.

1. Wound drainage
2. Remove the foreign bodies like sutures which are hanging loosely
3. Debridement and dressings
4. Antibiotic coverage

5. Thromboembolism and Deep vein thrombosis

Various physiological changes during the antenatal time will increase the risk of development of venous Thromboembolism. Changes like hypercoagulability, obstruction to venous flow by gravid uterus, hormonally induced changes in the venous flow and injury to the vessels contribute for this. During the immediate postpartum the rate of pregnancy related hypercoagulability will be at its maximum level.(32)

The average duration for the antenatal hypercoagulable state will become to its normal State by 3-4 weeks from the time of delivery. Maternal morbid obesity

thrombophilia's, weight gain during the antenatal time, history of previous DVT are some of the risk factors for developing VTE during postnatal period(33). Caesarean section itself is an independent risk factor for VTE.

The most common site for VTE will be left lower extremities. Some of the studies showed 82% of VTE in the lower extremities will occur on the left side (34). The incidence of venous thromboembolism is very less. The incidence during the first week of postpartum will be 9 per 10,000 deliveries. From there it drops to 1 per 10,000 deliveries at the end of the fourth week from the delivery. From there it will decrease slowly till 12 week of postpartum (35). Screening with appropriate imaging and heparin is the main stay of treatment.

6. Septic pelvic thrombophlebitis:

Septic phlebitis arises as an extension along venous routes and can cause thrombosis. It is often coexisting with lymphangitis. The ovarian veins also will get involved, because the upper part of uterus and the placental implantation site will be drained by the same. Some authors suggested that septic thrombophlebitis likely to involve one or both ovarian venous plexuses. In one fourth of these women will have the clot in the inferior vena cava. Occasionally it may extend to renal vein also.(36)

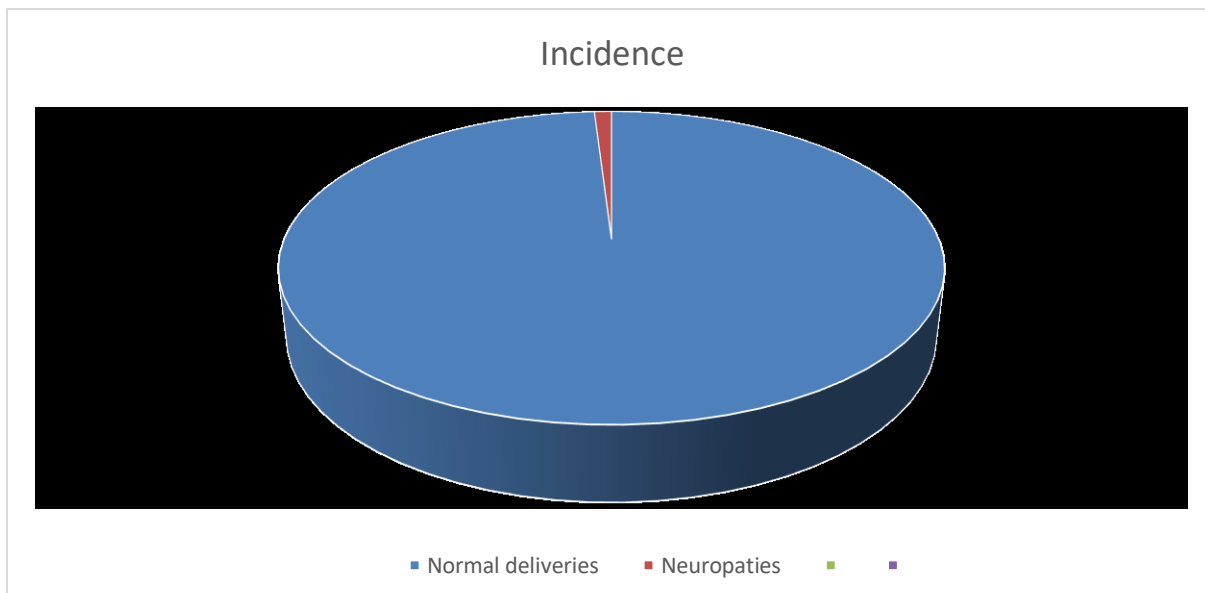
The incidence of the septic pelvic thrombophlebitis is 1 in 9000 with normal vaginal deliveries and 1 in 800 with cesarean deliveries. The overall incidence was 1 in 3000 deliveries(37).

The increased rate of cesarean section deliveries will increase the rates of pelvic thrombophlebitis. Even though the mortality rates have been reduced drastically recent days with the advent of newer antibiotics, rarely it can result in severe sepsis, thrombus in inferior vena cava and pulmonary embolism. Symptoms will be fever with chills and flank pain. Tenderness can be elicited on physical examination. Diagnosis can be done by doing pelvic CT or MRI pelvis or with the both.

Neuropathy:

Obstetric neuropathy is very rare with the incidence of confirmed nerve injury was only 1% among 6000 deliveries. Lateral cutaneous femoral neuropathy is most common neuropathy followed by femoral neuropathy.(38)

Figure 3- Incidence of Neuropathy among deliveries



Pressure on branches of lumbosacral plexus due to descent of head will cause intense pain on one or both legs during delivery. Pain may continue after the delivery due to injury of the nerve. Injury can result in various degree of sensory loss. In some cases, there can be foot drop due to injury at the level of lumbosacral plexus, sciatic nerve or common peroneal nerve.

Risk factors for developing neuropathy are nulliparity, prolonged second stage of labour, pushing the head for longtime in semi lithotomy position and regional anesthesia during labour (39). The average duration of symptom is 2 months and can range from 2 weeks to one and half year.(39)

Prospective observational study done by Richards et al, 1019 postnatal women were screened from the time of delivery till 32 hours postnatal. Out of 1019 women 2% women had signs of neurological deficits. Lumbosacral plexus injuries are the most common injuries. Mostly they have sensory deficits and half of these had motor deficits which did not impact functionally. (40)

A case control study done by Maigne JY et al reported that 7.3% of postnatal population had Coccydynia. Mostly these pains attributed to forceps delivery. Vacuum assisted deliveries also can cause Coccydynia. Fractures of coccyx also seen with normal vaginal deliveries.(41)

7. Musculoskeletal injuries:

Pain in the hips and pelvic girdle and lower extremities are caused by difficult deliveries because of stretching and tearing injuries. Most of these injuries are self-limiting. Pubic symphysis separation during delivery is very rare in recent days. The normal distance of symphyseal joint is 0.4 to 0.5cm. Anything more than 1cm is

diagnostic for symphysis pubis diastasis. Incidence ranging from 1 in 600 to 1 in 30,000 deliveries. This leads to severe pain and interference with the loco-motive function. Symptoms can manifest during the delivery or first 48hrs after delivery.

X ray pelvis will help in diagnosing this condition. Management will be conservative with the pelvic binders with analgesics. If symphyseal distance is more than 4cm will need surgery (42). Recurrence will be common for consecutive pregnancies. In that cases normal vaginal delivery is contraindicated and they advise to go for caesarean delivery.

8. Mental health problems:

It is accepted that after few days of delivery some mothers will exhibit the postpartum depression and mood swings. According to American College of Obstetrics and Gynecology (ACOG) it is vital to screen the women for postpartum depression, who had high risk factors. Etiology can be due to experiencing of fears during the antenatal time and postnatal time, postpartum discomfort, anxiety over the ability to provide newborn care, physical image concerns, and fatigue from sleep deprivation. Various studies from Asian continent reported the incidence and various etiological factors causing postpartum depression.

An observational study done from Tamil Nadu, by R J S Savirimuthu et al, evaluated 137 postpartum women for postpartum depression showed 26.3% of patients had postpartum depression. They found the associated factors for PPD are teen age and elderly age above 35years, recurrent pregnancy loss, unhappy marriage, domestic violence during antenatal period, having girl baby when desired for a boy baby at delivery, having a low birth weight neonate and having family history of depression, some of the strong associated factors were found during their evaluation.(43)

But Chandran et al from south India, had reported in their study the incidence of postpartum depression is only 11%. The risk factors for developing postpartum depression are low socioeconomic status, birth of girl baby, problems with mother-in-law and lack of physical help.(44)

Another study by Chandan Dubey et al from India have done a postpartum survey in 2011 in Delhi found that the incidence of postpartum depression in North India was 6%. The causative risk factors are similar like the above studies, some of them are female child birth, nuclear family and poor marital status had increased statistical significance for causing postpartum depression.(45)

A similar study done from North India by Gupta Swapan et al, in 2010 found that the incidence of postpartum depression among the women in North India was 15.8%. Out of which only 1% will suffer from Postpartum psychosis. The causative factors are having more than one girl child, low socioeconomic state and low educational status.(46)

Graphical representation of incidence of postpartum depression from various studies.

Category 1: R J S Savirimuthu et al.

Category 2: Chandran et al.

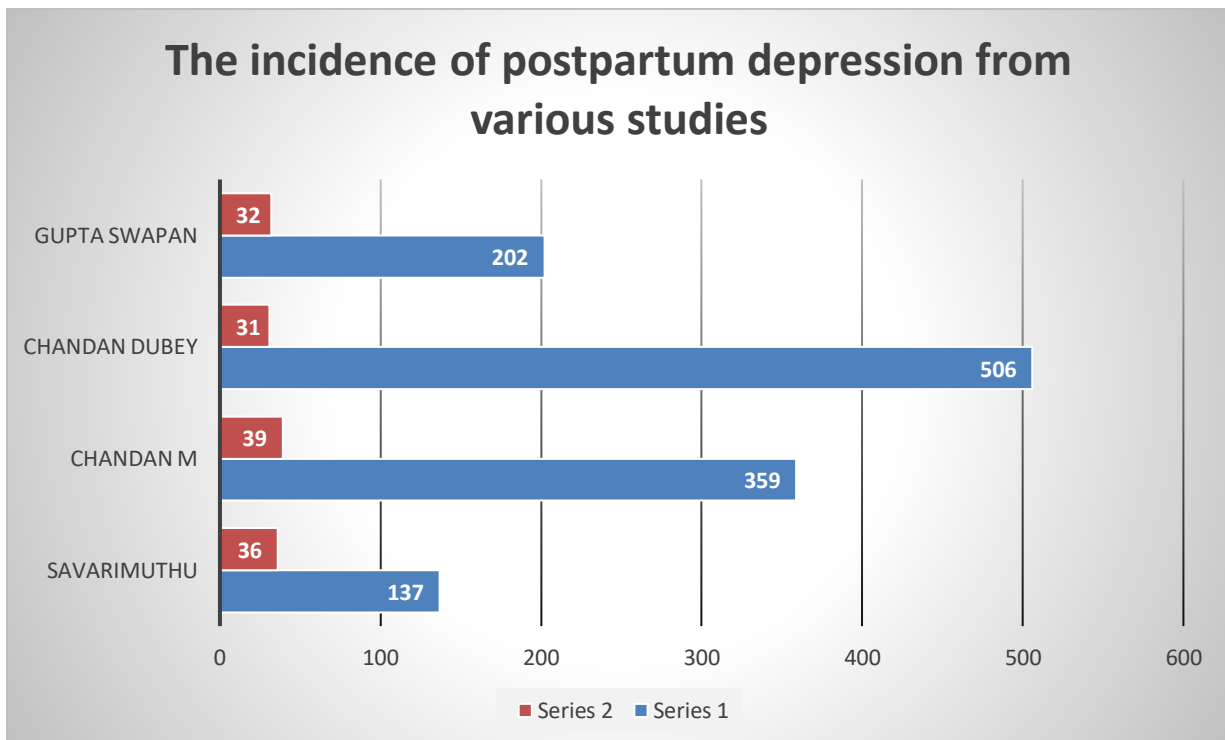
Category 3: Chandan Dubey et al.

Category 4: Gupta Swapan et al.

Series 1 is number of study patients.

Series 2 is the incidence.

Figure 4- Incidence of postpartum depression in various studies



9. Neonatal problems:

First 6 weeks after the delivery, neonates will have various nonspecific signs and symptoms which are mostly normal and sometimes they may be pathological also.

Jaundice, not feeding well, convulsions, drowsy or unconscious, movement only when stimulated or no movement at all, fast breathing (60 breaths per min), grunting, severe chest indrawing, raised temperature, $> 38^{\circ}\text{C}$, hypothermia, $< 35.5^{\circ}\text{C}$ and central cyanosis. If the neonate has any problems from above mentioned needs immediate attention and should admit the baby for further treatment.

A retrospective study done by Calado CS et al on the common characterization of symptoms and their prevalence among the neonates (< 28 days) who presented to emergency departments are following, 17.2% were referrals with complaints of Jaundice, excessive crying and rash. The primary diagnosis was made for nonapparent disease, infant colic, physiological jaundice. Only 13% of neonates needed hospital admission from out of 540 neonates.(47)

Millar KR et al studied 559 neonates retrospectively and their common causes for hospital visits were, feeding problems, difficulty in breathing, irritability and jaundice and sepsis. The incidence of these problems were 8.7%. (48)

Problems in newborns and early infancy which need hospital visit

Poor feeding, Lethargy, Irritability, Jaundice, Fever, Weight loss >10%, Breathing difficulty/Noisy breathing/Cough, Cyanosis and abnormal movements-seizures, not passing stools for >1week, abdominal distension and bilious vomiting.

Problems which can be reassured and can be managed with simple advices

Sneezing/ hiccups- Normal phenomenon

Possetting (small volume vomitus-curdled milk –following feeds)- Advise burping

Not passing stools daily- Advise adequate feeding and check weight- Only reassurance if weight gain present

More crying in night- Normal phenomenon, benign skin rashes normal.

Not enough milk or baby crying after feeds also- advise adequate feeding (direct breast feeds+ expressed breast milk –hind milk 10-15 ml 3-4 times a day) and check weight- Only reassurance needed to the parents if weight gain present; advise locally available lactagogues like garlic, fenugreek, adequate hydration and sleep for the mother

Crying or straining before and beginning of urination/passing stools- Normal phenomenon. In case any of the above symptoms persist/difficult to manage the parents can be advised to bring the baby to hospital.

PREVALENCE OF THE POSTNATAL COMPLICATIONS

An observational study done in Netherlands by de Groot N et al in 2018, follow up done for 1140 mother and baby pairs in the initial 10 days after postpartum by home visit, showed 55% of all mother-baby pairs experienced at least one complication (e.g. cracked nipples, >10% weight loss of the baby) and 5% at least one major complication (e.g. mastitis, cyanosis of the baby)(49)

A cross sectional study done in Brazil in 2016 by Kamila Juliana da Silva Santos et al on prevalence and factors associated with cracked nipples in the first month postpartum showed the prevalence of cracked nipples was 32 % in the first 30 days postpartum(18)

A study to investigate the problem faced by newly breastfeeding mother by Elwelely MZ (2018) in Egypt on 200 women in the postnatal period for 40 days showed ignorance about its importance of breast feeding, lack of support and insufficient breast milk (23.0%, 21.5% and 15.0 respectively). More than half of the sample (54.6%) was exposed to nipple and breast problems such as; nipple soreness and cracking, breast engorgement and nipple size problems (51.5%, 39.0% and 34.0% respectively) and 76.0% were exposed to postpartum stress(19)

A retrospective observational study done on 234 women in 2015 in Australia by Kent et al, on nipple Pain in Breastfeeding Mothers: Incidence, Causes and Treatments showed 36% of the consultation in the breast-feeding center are for nipple pain and improper technique of attachment is attributed for this(50)

A cluster randomized-control, placebo- control, community- based trial, done in Nepal in 2003- 2005 by Scafford CG et al, involved 18985 new born infants, to evaluate the effect newborn chlorhexidine cleansing on neonatal mortality and morbidity, new born follow up was done by home visits for 28 days after delivery, showed the incidence of referral for neonatal jaundice was 29.3 per 1000 live births. Male babies, large for gestation, breastfeeding technique, primiparity, skilled birth attendance, place of delivery, oil massage, paternal education and ethnicity were significant risk factors for having more referrals.(51)

Cross sectional quantitative study of Greek women's satisfaction on postnatal care done by Vasiliki et al in 2018, surveyed 300 low risk women who delivered a term healthy baby in a regional hospital in Greece to determine their satisfaction level of the postnatal care by a self-administered questionnaire. High satisfaction scores were documented for professional support 79.1% and continuity 70.1% and time with women 71.1%. Low satisfaction scores were documented on advice on contraception, social support and women's health. The study concluded that, in order to improve in patient centered care, advice on mother's health, baby care and breast feeding should be advised. Healthcare professionals must spend quality time with patients to improve the above.(52)

What did women do when they had concerns?

Most of the women in south India when they had problems related to postpartum, they were unable to access the proper help related to healthcare due to various social and financial obstacles. Most of them will be managing at home by the advice given by grandmother or a mother at home.

Studies done on telephonic support in various countries showed promising results. Women in developed countries were always be able to access the healthcare. A few studies done in developing countries on specific postnatal issues showed supportive and positive results. They were assuring and helpful for mothers regarding simple breastfeeding issues, routine neonatal care and management of fussy neonate.

A randomized controlled study done in Lebanon by Hibah Osman, 353 primi mothers were recruited, they were provided with the telephonic access throughout the day. Only 84 patients have used the telephonic access. Most of the calls related to general postnatal care, general neonatal care, breast feeding counselling and management of fussy new born. Most of the women who accessed the telephonic support were satisfied. 18.6% of calls out of those who called the healthcare provider through telephonic access required referral to hospital. 66% of calls were breast feeding and 23% for excessive crying of neonate.(53)

Other supports available for postnatal women are home visits by healthcare team and mobile clinics.

Protocol for repeat visits during postnatal time

According to the various authors most of the complications will occur during the first 2 weeks of postpartum. After 2 weeks the incidence of various complications will be very low. It is recommended that healthy mothers and neonates should remain in the health care facility for the first 24hrs. If the birth was at home, then the first postnatal visit should be within 24hrs. In general, the routine postnatal visit is recommended in between 4th week- 6th week.

According to the World Health Organization the mother and the baby pair must be seen by the healthcare providers by day 3rd, between 7-14days, and at 6 weeks after birth. Before discharge from the hospital mother's bleeding should be controlled, there shouldn't be any signs of infection for the mother as well as the neonate and neonate should be breast feeding well.(54)

According to ACOG 2018 bulletin, postpartum women should have an encounter with care provider by telephone or by person for acute issues up to a minimum 3rd week of postpartum. For ongoing issues patient should visit the care provider before 12 weeks of postpartum period.(55)

The Government of India recommend that all mothers and newborns should receive three postnatal checkups within 42 days of delivery as follows: first within 48 hours, second between 3-7 days and third within 42 days of delivery. But unfortunately, postnatal care is still very limited because of poor socioeconomic status and poor transport facilities (56). After getting discharged from the hospital, mother and the baby pair will be coming for postnatal checkup after 6weeks from birth. It may be because of various reasons.

In Our hospital the low risk postnatal mother and baby pair are getting discharged by day 3rd – 4th maximum. After that they will be seen only at 6th week postpartum if there is no problem during the 6 weeks duration. But high-risk postnatal women will be seen more frequently because of various complications.

Telemedicine can be alternative emerging facility to hospital visit in low risk postnatal women. Visiting hospital to see the clinician is not cost effective and time consuming. The neonate is exposed to infection if they come to hospital. If telephonic support to the low risk postnatal women can address the issues related to postpartum, then it will be cost effective alternate.

Evidence on telephonic support

Telemedicine holds the promise of improving access to health care, especially in areas where there are geographical barriers, and of reducing costs. Phone based technology has potential to improve the healthcare services in reproductive age women in developing countries. Telephonic support in developed countries showed improved breast feeding rates, depression states, contraception usage, improvement in quality of life and increased satisfactory rates with the hospital follow up.

A randomized control trial done by Jareethum R et al in 2008 in Thailand, 68 low risk pregnant women were recruited, and weekly text messages were sent by mobile phones to the study group from 28 weeks of gestational age till the delivery showed satisfaction in the study group was 9.25 vs 8.00 in control group, confidence levels were high in the study group 8.91 vs. 7.79 in control group and low levels of anxiety in the study group 2.78 vs. 4.93, but pregnancy outcomes were similar. The study shows the higher satisfaction level of pregnant women who received SMS via mobile phone during the antenatal service when compared with the general antenatal care group. The study also shows the higher confidence level and lower anxiety level in the antenatal period but no difference in pregnancy outcomes.(57)

A Randomized control trial done by Patel et al in 2018 in India, low risk pregnant women were recruited during the antenatal period and randomized and follow up done by weekly counseling and daily text messages, showed initiation of breast feeding within 24hrs of delivery was 37% in study group vs 24% in control group. Rate of exclusive breast feeding at 6 months was 97% in study group and 49% in control group. Mainly the duration of exclusive breast feeding was increased in telephonic supportive women(58)

A cluster randomized controlled trial done by S Lund et al in 2012 in Tanzania, involved 2550 women in 24 primary health centers. Messages were sent to the study group showed, mobile phone intervention was associated with an increase in skilled delivery attendance of 60% of the women in the study group versus 47% in the control group delivered with skilled attendance (odds ratio 5.73). The intervention produced a significant increase in skilled delivery attendance in urban women(59)

Cochrane review

A systemic Cochrane review done by Lavender T et al in 2013 on telephonic support of pregnant women and first 6 weeks postpartum, involved 27 randomized controlled trials, sample number of 12,256 women. All the trials were examined for telephonic support vs usual routine care. Most of the studies which included were conducted in the high resource settings. Most of the studies were examined for telephonic support provided for the mother's by clinicians. Few studies by peer's support and support by text messages. Most of the studies done on specific issues.

Women who received telephonic support during pregnancy, and after delivery had high satisfactory rates because of continuity of care.

The results of the two trials, women who received telephonic support showed low depression scores and less admission rates in neonatal intensive care units (NICU).

There is no definitive evidence on increase in duration of breast feeding, reduction in anxiety rates, cessation of smoking. Over all evidence is not clear but telephonic support may be promising intervention in specific situations(60). This study suggest current evidence doesn't support routine telephonic support for pregnancy and postpartum.

Our study will contribute to the knowledge of prevalence of the postnatal concerns in the 6 weeks postnatal period and assess whether the telephone can be an alternative to physical visit to the hospital to address concerns of the mother and the neonate during the postnatal period. If this proves effective, this can be adopted as a model to provide continued postnatal care facility.

METHODOLOGY

A prospective study to understand the low risk postnatal women's concerns by telephone communication during first 42 days period after delivery who delivered in Christian medical college Vellore, a tertiary referral center in South India.

The study protocol was reviewed and approved by the institutional review board prior to recruiting the patients. Patients were strictly selected according to the inclusion and exclusion criteria. IRB number: 11701 [Observational study]

Informed consent was taken from the low risk postnatal women at the time of discharge. Low risk postnatal women with 96hours hospital stay before discharge were recruited for the present study.

Inclusion criteria

Patients who had low risk antenatal and intrapartum and postpartum period are eligible for the study

Exclusion criteria:

GDM on OHA and insulin

Hypertension on medication, severe preeclampsia, eclampsia

Cardiac mothers

Multiple pregnancy

Any other major medical complications

Any complications during and after the delivery including PPH, anal sphincter injury
postpartum fever

ICU admission

Preterm deliveries

Anomalous baby/ still birth/baby admitted in NICU

The study was started in January 2019 and continued till August 2019. Patient recruitment was done from postnatal wards of Christian Medical College and Hospital, 2450 bed tertiary level center, Vellore.

A cohort of 271 patients recruited during the study period. Patients were provided the information sheet regarding the warning signs and symptoms and general postnatal information. Follow up was done by active phone call at the end of 2nd week and 4th week using a set of validated questions. Patients were asked to contact whenever they have any concern through phone. We documented each phone call from the patient as an event. The events are analyzed for frequency, distribution and for the association with clinical variables. We will be assessing the patient satisfaction at the end of 6 weeks during the routine postnatal visit in the hospital by a self-administered questionnaire

Algorithm of study planning

Patients who had low risk antenatal and intrapartum and postpartum period are eligible for the study.



Consent taken after giving information sheet which include detailed postnatal care materials to read and allowed to ask any clarification about it. Phone number from the patient is collected. Socio demographic, and clinical details are gathered.



Patients can call the PI through the phone number given from 9 am to 7pm during the 6week postnatal period. The patients are called back within 4-6 hrs. if the phone is not attended immediately (passive communication)

Each call is considered as critical events and the patient's concern are noted down. If needed, they are called to the hospital for detailed examination



The PI will call the patient at the end of 2nd and 4th week and enquired about the wellbeing of the mother and the baby with pre prepared questionnaire and the information will be noted. (active communication)



Analysis is done for the frequency, distributions of critical events, any association to the clinical variables and satisfactions of the mother on telephonic support

Primary outcome

To know the critical events (concerns) of the low risk postnatal women in the postnatal period.

Secondary outcomes

1. To assess the relation between the concerns of postnatal women and the socio demographic clinical variables
2. To assess the satisfaction level of the postnatal women on telephonic conversation in addressing their concerns

Table number: 1- Sample size calculation:

Single Proportion - Absolute Precision

	Breast	Abdomen	Digestion	Skin	Mastitis
Expected Proportion	0.136	0.075	0.277	0.129	0.264
Precision (%)	5	5	5	5	5
Desired confidence level (1-alpha) %	95	95	95	95	95
Required sample size	181	107	308	173	299

With reference to Nynke deGroot et al, The prevalence of adverse postnatal outcomes for mother and infant in the Netherlands. The prevalence of most common Postnatal outcome for mother were found to be Breast 13.6%, Abdomen 7.5%, Digestion 27.7%, Skin 12.9% and Mastitis 26.4% respectively. With a precision at 5% and a desired confidence interval at 95% considering the spectrum of outcomes we need to study at least 107 to 299 postnatal mothers who are accessible through mobile phone and willing to participate.

Formula

$$n = \frac{Z_{1-\alpha/2}^2 p(1-p)}{d^2}$$

Where,

p : Expected proportion

d : Absolute precision

1- $\alpha/2$: Desired Confidence level

Estimating single proportion (Absolute precision)

Reference

Lemeshow S, Hosmer DW, Klar J, Lwanga SK. *Adequacy of Sample Size in Health Studies*. John Wiley and Sons, 1990.

The sample is taken as 300.

Quantitative variables: Age and gestational age are quantitative variable, analysis done by mean and median.

Statistical methods:

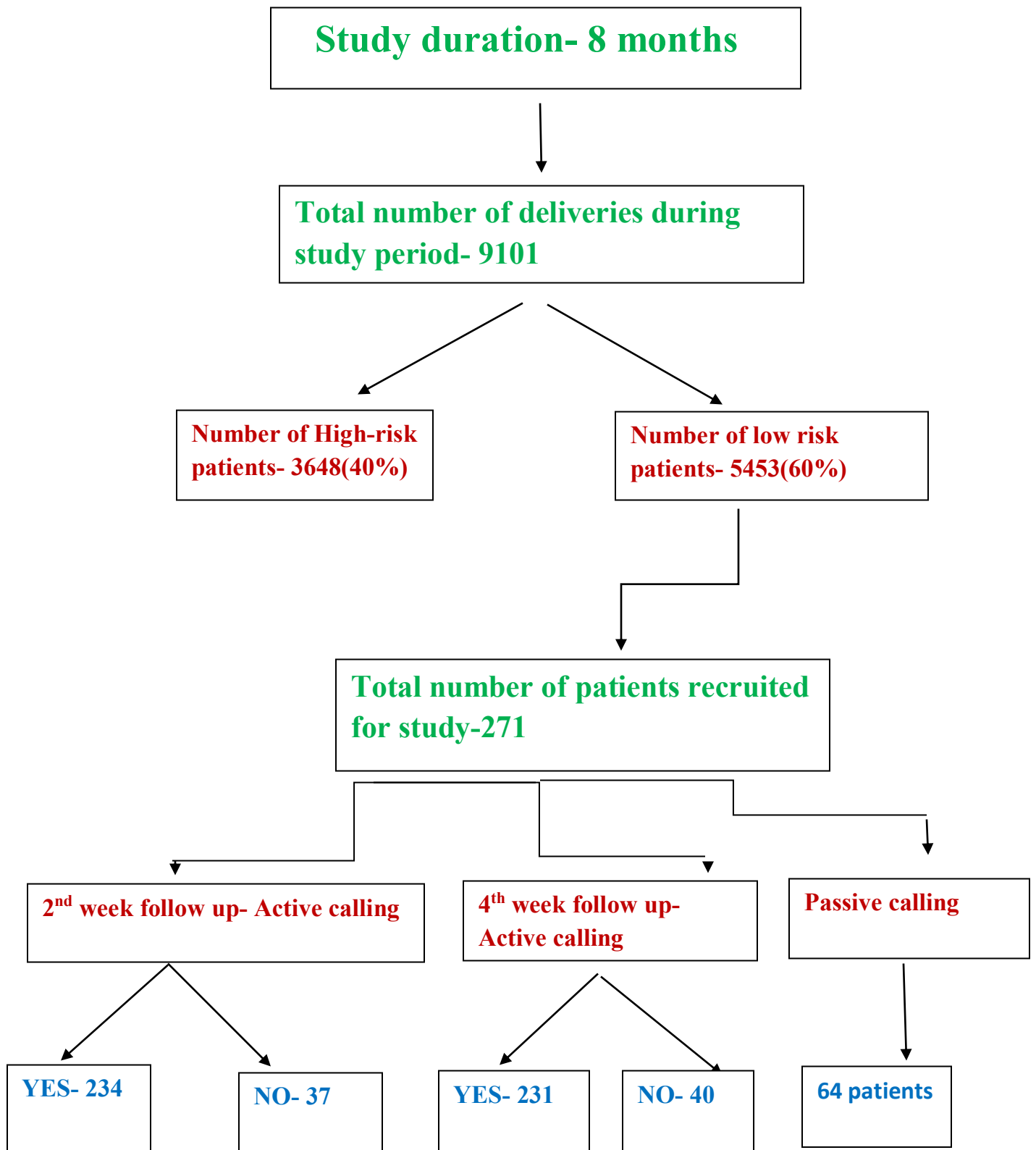
Data entry was done using EPI data3.1. Data analysis was done using SPSS 21.0. Descriptive statistics will be reported using Frequency and percentage for Categorical variable such as gender of the baby, Mode of delivery, postnatal complications etc. Mean +/- SD will be reported for continuous variable like age of the mother, Gestational Age. Most common risk factors among postnatal mothers will be reported using Frequency and 95%CI.

Results

The study was done over a period of 8 months from January 2019 to August 2019. The total number of deliveries during the study period is 9101. Out of 9101 mothers, low risk is 5453 (60%), high risk mothers are 3648 (40%). A cohort of 271 low risk mothers recruited during the study period. Till the last week of August 2019, follow-up was done for 271 low risk mother and baby pair. During the 2nd week 234 were contactable and 37 were not contactable. During the 4th week 231 mothers were contactable and 40 were not contactable. And we had 64 mothers called passively during the study time when ever they had concerns regarding mother and baby pair.

Mostly active calls were done during the day time. But passive calls were answered between 9am- 7pm for 6 weeks puerperal period. The reason for mothers who were not able to contact are wrong mobile numbers or didn't answer the phone call while active calling. Most of the passive calls answered in the day time but one mother called at 1am in night time.

CONSORT FIGURE



Baseline characteristics

Out of 271 patients, 256 were booked with Christian Medical College Hospital and 15 were booked elsewhere. 166 belongs to nuclear families and 105 belongs to joint families. 143 were primiparous women and 128 were multiparous women. Out of total number 131 delivered boy babies and 140 delivered girl babies. 181 mothers got discharged on 3rd postnatal day. 90 mothers got discharged at 4th postnatal day.

Figure 5- Day of discharge from the time of delivery

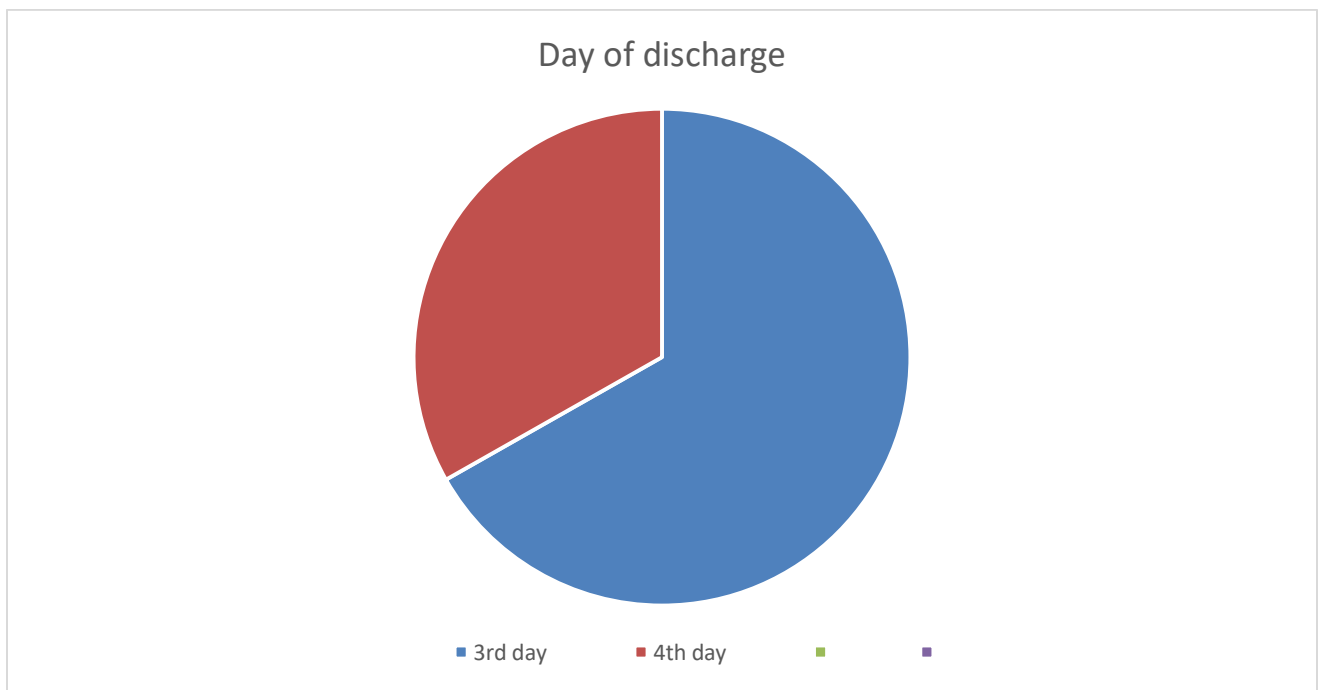
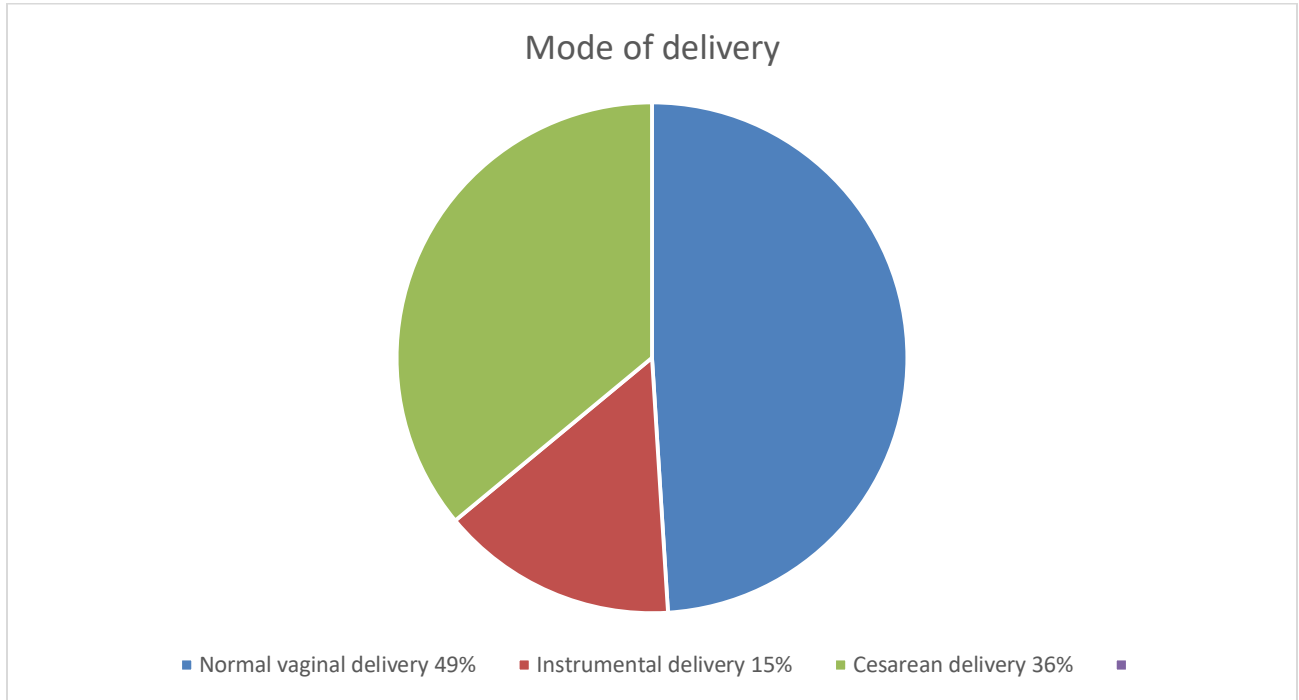


Figure 6- Mode of delivery

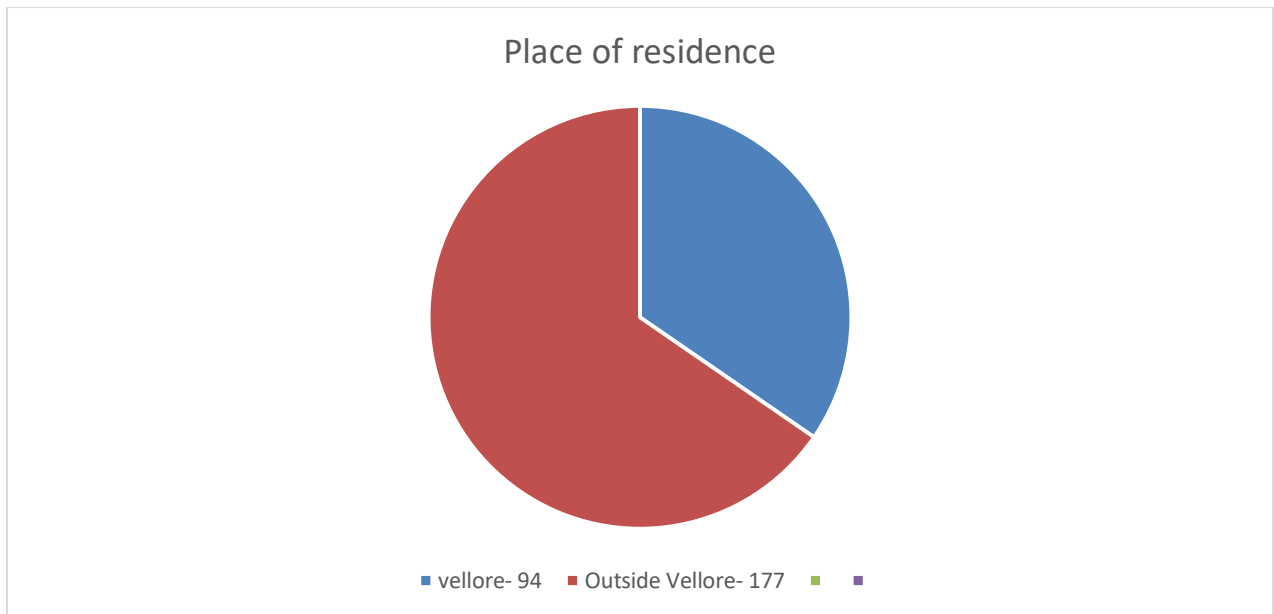
Mode of delivery- 133 (49%) mothers had normal vaginal delivery, 41(15%) had instrumental deliveries and 97 (36%) had Cesarean section.

	Frequency	Percent
Normal deliveries	133	49.1
Instrumental	41	15.1
Cesarean	97	35.8
Total	271	100.0

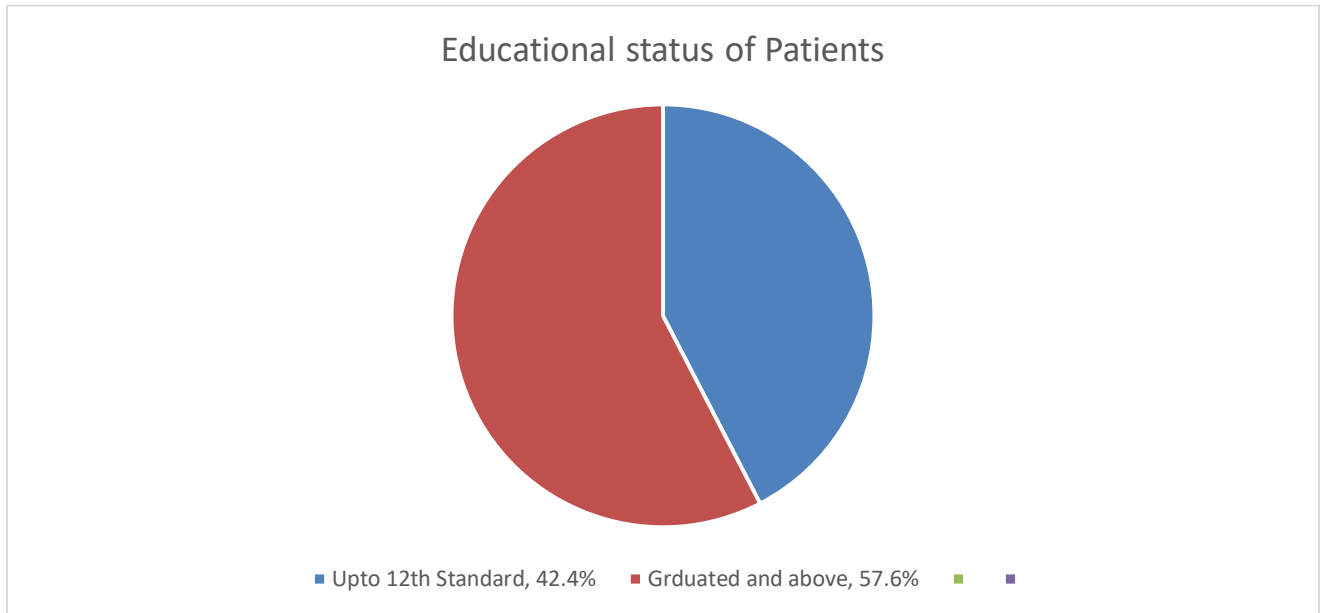
Table 2.2- Mean age of the mothers, family income, baby birth weight, duration of calling.

Variables	N	Minimum	Maximum	Mean	Std. Deviation
Family Income per month (Rupees)	269	3000	90000	19860.59	14801.236
Age of the patient (Years)	271	17	40	25.87	4.026
Birth weight (Kilogram)	271	2.20	3.92	2.9986	.35221
Duration of calling (2nd week) (Seconds)	234	120	1802	199.35	120.935
Duration of calling (4th week) (Seconds)	231	60	1202	132.12	75.518

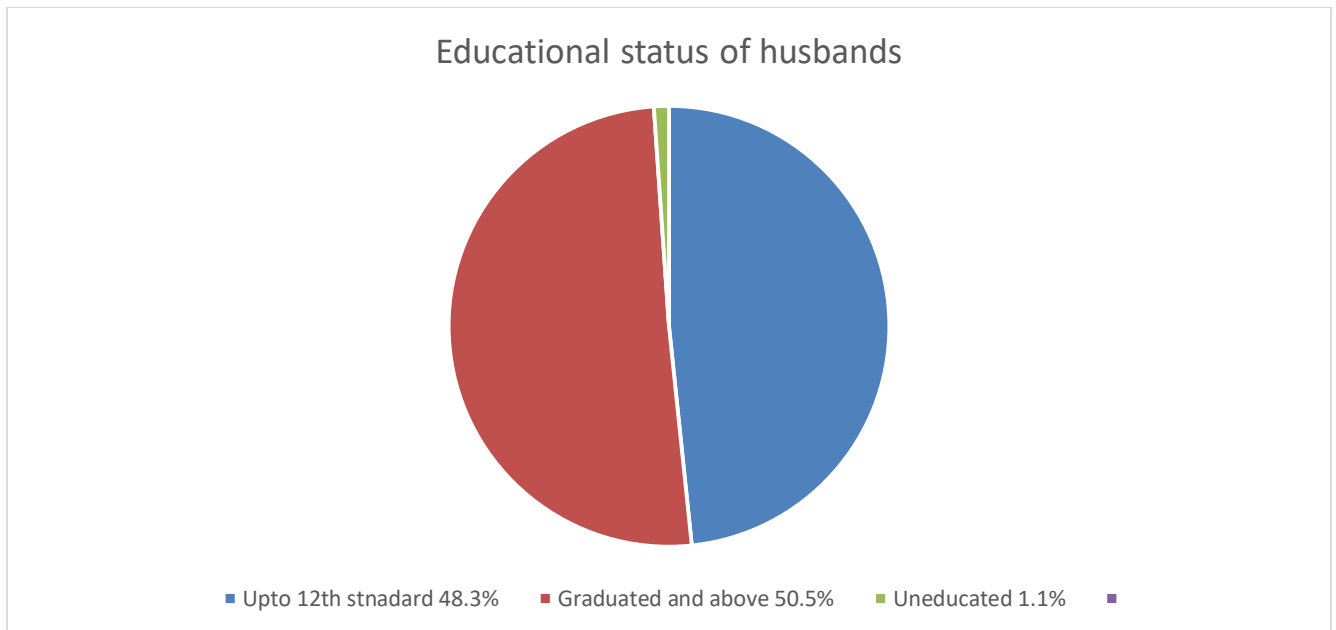
The maximum income observed was 90000 rupees, the minimum is 3000 rupees per month. The youngest is 17 years old and oldest is 40 years old. The Mean birth weight is 2.9kg. Duration of calling during the 2nd week is minimum 2 minutes and maximum 30 minutes with mean duration is 3 minutes 9 seconds. The mean duration of 4th week active calling is 2 minutes and 12 seconds

Figure 7- Residence

More than half of the Mothers are from outside Vellore. 94 mothers are from Vellore and 117 are from outside Vellore.

Figure 8.1- Educational status of mothers

Educational status of the mothers: 115 were studied up to 12th standard and 156 were graduated from college.

Figure 8.2- Educational status of husbands

Out of 271 husbands, 131 were graduated, 137 were studied up to 12th standard and 3 were uneducated.

CRITICAL EVENTS AT 2ND WEEK DURING ACTIVE AND PASSIVE CALLING FOR MOTHERS.

Table 2.4- Critical events for mothers before 2nd week follow up.

Critical event name	2nd week
Wound	16
Fever	5
UTI	5
Bowel related	4
Secondary PPH	2
Breast related	2
Miscellaneous	5
Total	39

We found the total of critical events for mother before the active calling was 39 for which they consulted the clinician already.

Table 2.5- Critical events for mothers during the 2nd week of active calling

Critical event name	2nd week
Wound (Cesarean, episiotomy)	28
Breast related (soar nipple, breast pain)	18
UTI	6
Fever with abnormal discharge	4
Secondary postpartum hemorrhage	3
Bowel related (constipation, loose stools)	2
Total	61

Total number of critical events or concerns for mother at the 2nd week active calling is 61.

Total number of critical events for mothers at the end of 2nd week active calling is 100 events (39 events before 2nd week+ 61 events at the time of 2nd week calling)

Table 2.6- Critical events for mothers during 2nd week of passive calling

Critical event name	2nd week
Episiotomy/ Cesarean wound events	13
Fever	5
Bowel issues (loose stools/constipation)	3
Breast feeding issues	3
Secondary postpartum hemorrhage	2
Miscellaneous	5
Total	31

SUMMARY OF 2ND WEEK ACTIVE AND PASSIVE CALLING FOR MOTHERS**Table 2.7- Summary of 2nd week events**

CRITICAL EVENT	2nd week active calling	2nd week Passive calling	Total number of events	% of events
Wound	44	13	57	43.5%
Breast related	20	3	23	17.5%
UTI	11		11	8.39%
Bowel related	6	3	9	6.87%
Secondary PPH	5	2	7	5.34%
Fever	9	5	14	10.68%
Miscellaneous	5	5	10	7.63%
Total events	100	31	131 Events	

We found wound concerns (43.5%) are first followed by breast feeding issues (17.5%), fever (10.68%) and Urinary tract infections (7.39%) are major concerns in low risk postnatal mothers by the end of 2nd week.

CRITICAL EVENTS AT 4TH WEEK DURING ACTIVE AND PASSIVE CALLING FOR MOTHERS.

Table 2.8- Critical events for mothers before 4th week follow up

Critical event name	Frequency
Wound	3
Breast feeding	2
Fever	2
Miscellaneous	2
Total	9

Table 2.9- Critical events for mothers during 4th week follow up

Critical event name	Number
Wound	10
Breast feeding	9
Bowel related	3
Urinary tract infection	2
Lower abdominal pain	1
Total	25

Critical events for mothers at the end of 4th week by active calling is 34 events, among which wound and breast-feeding concerns are major events during 4th week follow up.

Table 3.0- Critical events for mothers during the 4th week of passive calling

Critical event name	4th week
Bowel issues (loose stools/constipation)	8
Breast feeding issues	3
Lower abdominal pain	2
Urinary tract infection	2
Episiotomy/ Cesarean wound events	1
Fever	1
Secondary postpartum hemorrhage	1
Miscellaneous	2
Total	20

SUMMARY OF 4TH WEEK ACTIVE AND PASSIVE CALLING FOR MOTHERS**Table 3.1- Total events during 4th week**

CRITICAL EVENT	4th week	4th week passive calling	Total number of events	% of events
Wound	13	1	14	25.9%
Breast related	11	3	14	25.9%
UTI	2	2	4	7.40%
Bowel related	3	8	11	20.37%
Secondary PPH		1	1	1.85%
Fever	2	1	3	5.55%
Miscellaneous	3	4	7	12.96%
Total events	34	20	54	

By the end of the fourth week the number of concerns for mothers has come down to 1/3 of its 2nd week concerns. Wound concerns (25.9%), breast feeding (25.9%) related and

bowel related (loose stools and constipation) (20.37%) are the major concerns for mothers.

COMPARISION OF 2ND WEEK AND 4TH WEEK ACTIVE AND PASSIVE CALLING FOR MOTHERS

Table number: 3.1- showing total events for mothers during the study period

CRITICAL EVENT	2nd week Active calling	2nd week Passive calling	4th week Active calling	4th week passive calling	Total number of events	% among 271 patients
Wound	44	13	13	1	71	26.19 %
Breast related	20	3	11	3	37	13.65 %
UTI	11		2	2	15	5.53 %
Bowel related	6	3	3	8	20	7.40 %
Secondary PPH	5	2		1	8	2.95%
Fever	9	5	2	1	17	6.27%
URI	2			1	3	1.10 %
Miscellaneous	3	5	3	3	14	5.13 %
Total events	100	31	34	20	185-Events	

Major events for mothers during our study period were events related to wound (Cesarean or episiotomy). The common concerns for wound are pain, discharge, redness and wound gaping are the major events. Secondly, we found breast feeding related issues like crack nipple, pain while feeding, breast engorgement and breast abscess. Bowel complaints are like loose stools or constipation. Few miscellaneous calls are for the following 4 mothers had chickenpox, 1 mother has thrombophlebitis, 2 mothers had ear

pain, 3 mothers had queries regarding hospital bill, 3 had Upper respiratory tract infection and 4 had lower abdominal pain. All together at the end of study period we found 185 concerns for mothers.

CRITICAL EVENTS FOR BABIES AT 2ND WEEK ACTIVE AND PASSIVE CALLING

Table 3.2- Critical events for babies before 2nd week of active calling

Critical event name	Frequency
Cold	13
Excessive crying	6
Loose stools	5
Discharge from umbilicus	5
Crying while passing urine	3
Ear discharge	1
Eye discharge	1
Aspiration of milk	1
Fever	1
Jaundice	1
Total number	37

Table number: 3.3- Critical events for babies during 2nd week of active calling

Critical event name	Frequency
Jaundice	1
Ear discharge	1
Swelling at vaccination site	1
Vaccination information	3
Total	6

Total critical events for babies at the end of 2nd week by active calling is 43 events.

Table 3.4- Critical events for babies during the 2nd week of passive calling

Critical event name	2nd week
Excessive crying	3
Discharge from the umbilicus	2
Vomiting after feeding	1
Loose stools	1
Spotting per vagina	1
Total	8

SUMMARY OF EVENTS FOR BABIES DURING 2ND WEEK OF ACTIVE AND PASSIVE CALLING

Table number: 3.5- Total events for babies during the study period

Critical event	At 2nd week active calling	2nd week Passive calling	Number of total events	% of events
Common cold	13		13	25.49%
Loose stools	5	1	6	11.76%
Excessive crying	9	3	12	23.5%
Discharge from the umbilicus	5	2	7	13.72%
Ear discharge	2		2	3.92%
Eye discharge	1		1	1.96%
Fever	1		1	1.96%
Jaundice	2		2	3.92%
Miscellaneous	5	2	7	13.72%
Total	43	8	51 events	

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We found total of 51 events for babies at the end of the second week follow up.

The major ones are common cold 25.4%, excessive crying 2.35% and discharge from the umbilicus 13.72%.

CRITICAL EVENTS FOR BABIES AT 4TH WEEK ACTIVE AND PASSIVE CALLING

Table number: 3.5- Critical events for babies before 4th week of active calling

Critical event name	Frequency
Cold	4
Vomiting	2
Jaundice	1
Discharge from the umbilicus	1
Miscellaneous	3
Total number	11

Table 3.6- Critical events for babies during 4th week active calling

Critical event name	Frequency
Excessive crying	1
Jaundice	1
Total	2

Total number of critical events at the end of 4th week by active calling – 13 events.

Table 3.7- Events for baby during passive calling.

Critical event name	4th week
----------------------------	----------------------------

Immunization	3
Loose stools	2
Rashes over the body	2
Vomiting after feeding	1
Cold	1
Total	9

TABLE 3.8- SUMMARY OF EVENTS FOR BABIES DURING 4th WEEK OF ACTIVE AND PASSIVE CALLING

Critical event	At 4 th week active calling	4 th week passive calling	Number of total events	
Common cold	4	1	5	22.72%
Loose stools		2	2	9.09%
Excessive crying	2		2	9.09%
Discharge from the umbilicus	1		1	4.54%
Eye discharge	1		1	4.54%
Jaundice	2		2	9.09%
Miscellaneous	3	6	9	40.90%
Total	13	9	22 events	

Babies had 22 events at the end of 4th week follow up. Major ones are cold (22.72), loose stools 9% and excessive crying 9%. The number events are reduced to half comparing from the 2nd week of follow up.

COMPARSION OF 2ND WEEK SUMMARY AND 4TH WEEK ACTIVE AND PASSIVE CALLING FOR BABIES.

Table 3.9- Total events for babies during the study period

Critical event	At 2nd week active calling	2nd week Passive calling	At 4th week active calling	4th week passive calling	Number of total events	% events among 271 babies
Common cold	13		4	1	18	6.64 %
Loose stools	5	1		2	8	2.95 %
Excessive crying	9	3	2		14	5.16 %
Discharge from the umbilicus	5	2	1		8	2.95 %
Jaundice	2		2		4	1.47 %
Vomiting after feeding		1	2	1	4	1.47 %
Miscellaneous	9	1	2	5	17	6.21 %
Total	43	8	13	9	73	

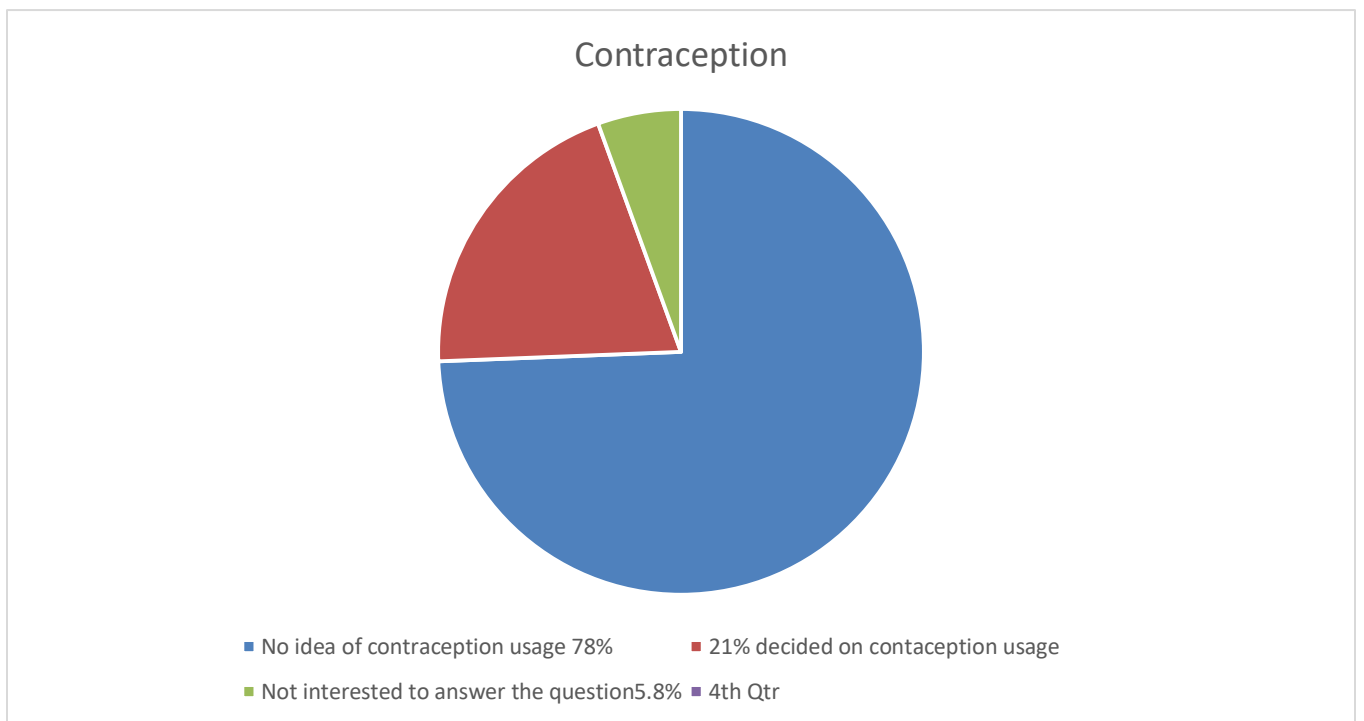
Babies had a total of 73 events. Out of that the major events are common cold 6.64%, excessive crying 5.16%, loose stools 2.95%, discharge from the umbilicus 2.95%. The miscellaneous calls for the following are 4 had jaundice, 4 had vomiting after

feeding, 2 had rashes over the body, 1 aspirated milk, 1 had spotting per vagina, 1 had abscess at the vaccination site.

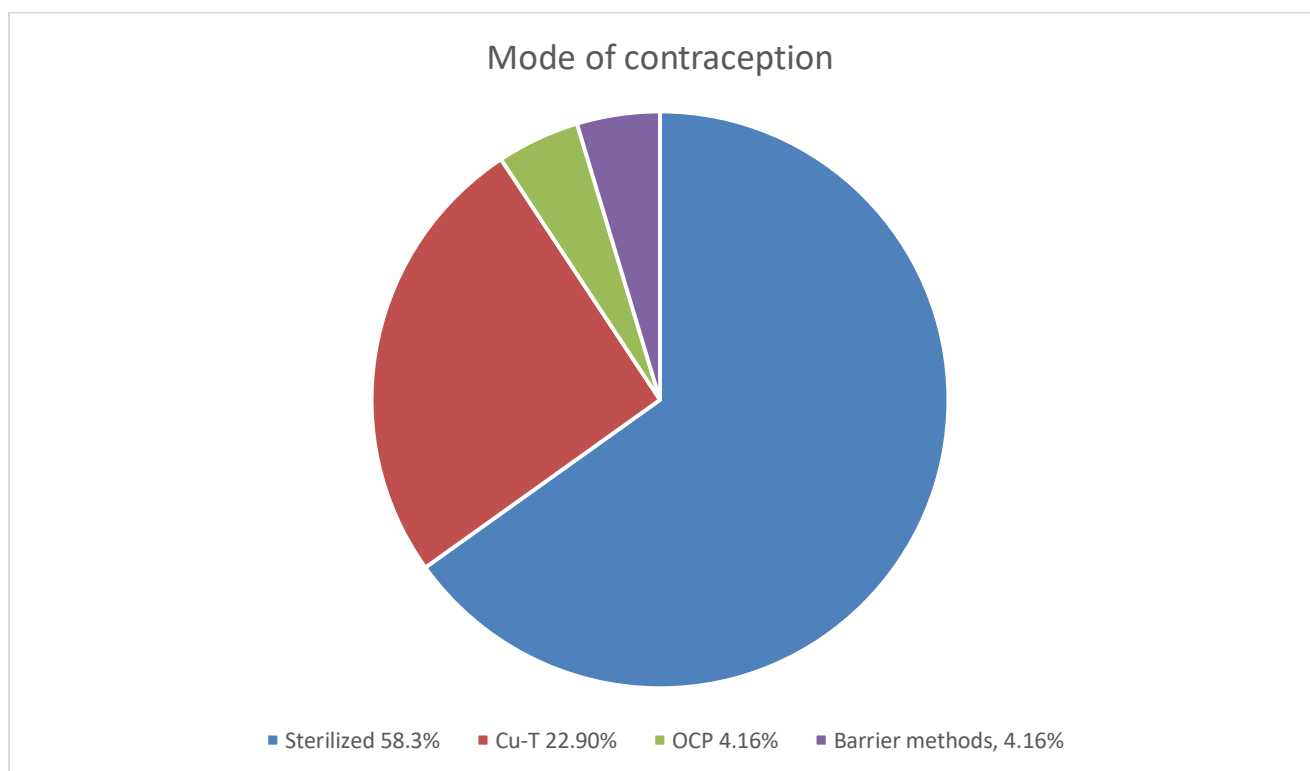
On active calling we found 270 mothers are taking their Iron and calcium supplementation daily, only 1 patient was not complaint with the tablets because of gastritis. 225 mothers are taking mixed diet and 9 mothers were pure vegetarians. Most of them are consuming water more than 3 liters per day.

Out of 231 mothers 98% were giving exclusive breast feeding, 2% were not able to give exclusive breast feeding due to inadequate milk secretion. Most of the babies are active, except one was lethargic.

Most of the mothers were staying at the mother's place at 2nd week postpartum as a tradition and custom. Only 2 were staying at husband's place, because they are multiparous women. We found in our study that if mother is staying at her mother's place, they are not having problems related to depression. The reason for not having postpartum depression while they are in mothers place is not known. They are not able address their mental health issues during the short time of conversation.

Contraception knowledge:**Diagram number: 9- Knowledge of contraception usage among mothers**

Out of 221 who answered questions related to contraception, 48 mothers decided about the mode of contraception. 172 patients had no idea of contraception. 13 mothers were not interested in answering the question.

Figure 10- Mode of contraception

Out of 48 patients who had decided on mode of contraception, >50% of mothers already underwent abdominal puerperal sterilization. 11 mothers had decided on Copper-T as a contraceptive, 2 mothers on Oral contraceptive pills and 2 patients decided on

barrier methods and 5 mothers were not able to decide on mode of contraception, but they were keen on contraception usage.

Relation between the critical events with socio demographic variables.

Bivariate analysis of mother's wound problem and socio demographic factors

Variable	Values	No Wound Infection [Numbers]	Wound infection [Numbers]	P value	Odds ratio	Confidence Interval
Income	Low	112	42	0.342	0.762	0.434- 1.33
	High	91	26			
Occupation	Housewife	187	62	0.806	1.131	0.424 – 3.01
	Other occupations	16	6			
Education	Below 10 th std	49	19	0.531	0.821	0.442- 1.52
	Above 10 th std	154	49			
Mode of delivery	vaginal	137	37	0.052	1.739	0.993-3.04
	Cesarean	66	31			
Booking status	Booked	195	59	0.009	3.77	1.315-10.85
	Un booked	7	8			
Parity	Primi gravida	107	36	0.974	0.991	0.572-1.71
	Multi gravida	96	32			
Type of family	Nuclear	127	39	0.445	1.243	0.711-2.17
	Joint	76	29			
Day of discharge	3 rd day	132	43	0.789	1.081	0.611-1.91
	4 th day	71	25			

Bivariate analysis of mother's breastfeeding problem and socio demographic factors

Variable	Values	No breastfeeding events [Numbers]	Breastfeeding event [Numbers]	P value	Odds ratio	Confidence Interval
Income	low	117	10	0.761	1.157	0.451- 2.96
	high	91	9			
Occupation	Housewife	194	17	0.536	1.630	0.342-7.77
	Other occupations	14	2			
Education	Below 10 th std	49	19	0.531	0.821	0.442-1.52
	Above 10 th std	154	49			
Mode of delivery	vaginal	138	11	0.458	1.434	0.552-3.72
	Cesarean	70	8			
Booking status of mother	Booked	199	19	0.383	0.913	0.876-0.95
	Un booked	8	0			
Parity	Primi gravida	109	14	0.075	0.393	0.137-1.13
	Multi gravida	99	5			
Type of family	Nuclear	126	12	0.825	0.896	0.339-2.37
	Joint	82	7			
Day of discharge	3 rd day	136	11	0.513	1.374	0.529-3.56
	4 th day	72	8			

Bivariate analysis of baby's critical events and socio demographic factors

Variable	Values	No neonatal events [Numbers]	Neonatal events [Numbers]	P value	Odds ratio	Confidence Interval
Income	Low	100	27	0.541	0.813	0.419- 1.57
	High	82	18			
Occupation	Housewife	170	41	0.590	1.382	0.424-4.50
	Other occupations	12	4			
Education	Below 10 th std	44	10	0.783	1.116	0.511-2.43
	Above 10 th std	138	35			
Mode of delivery	vaginal	116	33	0.225	0.639	0.309-1.32
	Cesarean	66	12			
Booking status of mother	Booked	176	42	0.205	2.514	0.578-10.94
	Un booked	5	3			
Parity	Primi gravida	96	27	0.382	0.744	0.383-1.445
	Multi gravida	86	18			
Type of family	Nuclear	114	24	0.252	1.467	0.760-2.83
	Joint	68	21			
Day of discharge	3 rd day	115	32	0.319	0.697	0.342-1.42
	4 th day	67	13			

The secondary outcome is to see the relation between the critical events with the sociodemographic variables. Most of the critical events had no relationship with sociodemographic variables except the wound concerns with booking status. Un booked mothers are having 3.7 times risk of having more wound infection comparatively with booked mothers. The P value is 0.009 with confidence interval of 1.315-10.85 and odds ratio of 3.77. Rest of the events for mother as well as baby has no relation with sociodemographic variables regarding their frequency.

Discussion

In developing countries, low utilization of postnatal care has been related to lack of knowledge about its importance, lower level of education, lack of access to health services, lack of counselling of postnatal care in institutional deliveries and women's tendency to give priority to health needs of their infants than their own health.

Another major factor for non-utilization of postnatal care is socio culture practices with child birth such as maternal seclusion after delivery and cultural beliefs in the community. According to the 2005-06 National Family health Survey (NFHS-3), only 42% of women reported receiving postnatal check-up after their recent birth. Utilization of postnatal care influences both women and children's lives, by recognizing the complications at the earliest and reduces repeat pregnancies by increasing acceptance of contraceptives (61).

In our study, 23.61% of study population passively called the principle investigator between 9am in the day to 7pm in the night. Total passive calls during the study time was 64. The average duration of the passive calling is 3 minutes. 75% events are raised for mothers and 25% for babies. 76% of concerns are raised by mothers and 23% by the family members. Similar study done in Lebanon in 2010, 24% of mothers used hotline postnatally (53).

Mothers had 39 events before the investigator called them and already seen by the outside clinician by the end of 2nd week. At the time of calling by the principle investigator, we found total of 61 events for mothers. And by passive calling mothers had 31 events by the end of 2nd week of postpartum. They had a total of 131 events by the end of 2nd week of postpartum. Out of 131 total events, 47% were for wound related, 17.5% events for breast feeding related, 8.3% for urinary symptoms, 10.68% for fever related, 6.8% for bowel related 5.34% for excessive bleeding per vaginum and 7.6% for miscellaneous. By the above observations most of the concerns are taking place by 2nd week of postpartum for mothers.

Between 2nd and 4th week the postpartum mothers had total events of 54. Out of which 9 events before 4th week calling, 25 events at the time of calling and 20 events by passive calling. Major events during 4th week follow up are wound related (25%) and breastfeeding related (25%).

The incidence of maternal events at 2nd week vs 4th week of postpartum are wound related events 57 vs 14, breast related 23 vs 14, excessive bleeding per vaginum 7 vs 1, urinary symptoms 11 vs 4. The major events for mothers from our study are wound related concerns 26.19%, breast feeding related 13.65%, loose stools and constipation 7.40%, fever 6.27%, urinary tract symptoms 5.53%, excessive bleeding per vaginum 2.95% and miscellaneous 5.13%. The incidence of maternal events reduced from 131 to 54 events from the 2nd week to 4th week of postpartum.

An observational study was done by de Groot et al. in Netherlands 1120 mothers and baby pairs were recruited and followed for first 10 days of postpartum by home visits to see the prevalence of postpartum complications for mother and baby pair. They found 13.6% of mothers had crack nipple, 1.3% had acute mastitis, 0.8% with abdominal pain and 0.8% had endometritis. For babies they found 27.7% of babies with digestion problems, 0.5% babies with drowsiness and 0.5% babies with low temperature.

Our study is consistent with studies quoted in the review articles by Cathryn MA Glazener et al. on the prevalence of various postnatal complications during 6 weeks of postpartum. 11-40% of mothers had wound problems (perineal wound pain and infection, women with post Cesarean wound infection and wound breakdown), 8-45% of mothers had breast problems (crack nipple, mastitis, breast engorgement insufficient milk secretion), 25-30% of mothers with postnatal anemia, and 10-20% mothers with postpartum depression, 4-16% of mothers reported secondary postpartum hemorrhage and 3-17% of mothers with UTI (62). An observational study done by Joseph L et al showed the prevalence of Cesarean wound infection as 9.8% within first 30 days of postpartum.

A retrospective observational study done on 234 women in 2015 in Australia by Jacqueline c. Kent et al, on Nipple Pain in Breastfeeding Mothers: Incidence, Causes and treatments showed 36% of the consultation in the breast-feeding center are for nipple pain and improper technique of attachment is attributed for this.

Secondary PPH is one of the life-threatening events during postpartum. The incidence of secondary PPH is 0.5-2% by Akladios C Y et al. We found 2.9% of mothers had concerns of excessive bleeding in our study. However, the severity of the PPH in terms of hospital admission, blood transfusion and any procedure done was not followed up.

Babies had a total of 51 critical events by 2nd week. Out of which 25% events are for common cold, 23% for excessive crying, 13% for umbilical discharge, 11% for loose stools and 25% miscellaneous.

Babies had a total of 22 events between 3rd week and 4th week of postpartum. Most of the events are common cold, loose stools and excessive crying. The total events for babies at the end of 2nd week is 51 and at the end of 4th week is 22. The incidence has reduced to more than half by the end of 4th week postpartum.

The major concerns for babies from our study are common cold 6.64%, excessive crying 5.16%, discharge from the umbilicus 2.95%, loose stools 2.95%, and miscellaneous 6.21%.

A retrospective study done by Calado CS et al on the common characterization of symptoms and their prevalence among the neonates who presented to emergency department are 17.2% referrals for jaundice, excessive crying and skin rash. Only 13% of neonates required admission out of 540. Millar KR et al studied 559 neonates in respective to their reasons for hospital visits showed 8.7% of neonatal problems are feeding problems, irritability, jaundice and sepsis.

We found most of the calls for baby during our study time is for common cold, loose stools, excessive crying and for vaccination information. An observational study done by Osman et al through hotline (2010), found most of the concerns are related to routine care, sleep patterns, circumcision care, umbilical care, fussiness and crying.

In our study we recruited 271 mothers, but we could able to follow 234 at 2nd week and 231 at 4th week of postpartum. During the active calling most of the times the principle investigator contacted the mothers during the evening times between 4-7pm. But few patients gave phone numbers which are not in use. Accessing the mobile phones was the toughest challenge faced by the PI. Language and literacy of the mother and technical problems are minor. For passive calling only 64 mothers used the services. The passive calls were made by the mothers.

A telephonic supportive study done by Islam et al in Bangladesh (2014) to improve diabetes patient's follow up and to improve self-care, had numerous issues like our study in terms of designing the client centered programs including phone access, sharing mobiles, language, literacy, privacy and technical challenges.

Telephonic follow up for different health aspects had positive results. Telephonic support done in developed countries for specific health issues like breast feeding support, postpartum depression, to improve in institutional deliveries and follow up of diabetic patients in Bangladesh had showed positive effect.(63)

A Randomized control trial done by Patel et al in 2018 in India, low risk pregnant women were recruited during the antenatal period and randomized for follow up by weekly counseling and daily text messages showed initiation of breast feeding within 24hrs of delivery was 37% in study group vs 24% in control group ($P < 0.001\%$). Rate of exclusive breast feeding at 6 months was 97% in study group and 49% in control group ($P: 0.001\%$). Mainly the duration of exclusive breast feeding was increased in telephonic supportive women. (58). Telephonic support has potential to improve follow up and early intervention of complications which will reduce the morbidity in mother and baby

Postnatal time is least concerning for mother as well as for the family because of various traditional and social customs. Poor economic status is one of the major factors in any health care follow-up program. Any critical event or concern during the postnatal period may be a small one for clinician and her family members, but for mothers it may be a significant concern. There is no quantification to measure the seriousness of all concerns. But it is important to address the concerns as early as possible to reduce the morbidity related to illness and increase her confidence in taking care of the baby.

With the available knowledge on the maternal and neonatal concerns from our study, an antenatal or postnatal education programme can be planned to educate the mothers and care takers.

From our observation most of the maternal and neonatal concerns are happening within in first 2 weeks' time of post-partum. It is drastically reduced by the end of the fourth week for mothers as well for babies. Mothers had total of 131 events by the end of 2nd week and by the end of 4th week they had only 54 events. By the end of 2nd week babies had 51 events, by the end of 4th week they had only 22 events. So, by the end of the 4th week the incidence of various events reduced to half from 2nd week events. Continued support to mother and baby pair for initial 2 weeks postpartum by visits of mother-baby pair to a specialized postpartum clinic or visiting the mother-baby pair by a maternity health nurse at home or giving continued telephonic support by healthcare team will meet the health need of the mother and her baby. A specialized postnatal clinic run by trained

healthcare person will minimize the burden of the family on hospital visit by the mother and baby pair. Home visit by a trained person on wound care, breast feeding can be done for early identification of maternal and neonatal complications. These will help the family by avoiding long waiting hours in the hospital and less exposure of the neonate to hospital environment.

A retrospective study was done by Clapp MA et al in 2011 in USA to see the rate of readmission and the causes for readmission during first 6 weeks of postpartum period. They found the incidence of readmission was 2.16%. The most common reasons for readmission are wound infection 15.5%, hypertension related 9.3% and psychiatric illness 7.7% (64). But our study was not designed to follow up of the critical event. Follow up of critical events will give information on magnitude of the critical events reported by the mother.

Cross sectional study done by Bhavya S Rao et al in South India on 2500 nursing mothers found 43% mothers were aware of contraceptive usage and 57% of study population were not aware of contraceptive usage (65). An observational study done by Bajracharya A et al in Nepal on 400 postpartum women enquiring about contraceptive knowledge showed 90.8% were aware of contraceptive usage. Most of them had used contraception in the past inter pregnancy intervals. Out of which 60.5% used oral contraceptive pills. They found the source for information was media.(66). In our study, on questioning through telephone 172 patients [78%] has not decided on which

contraceptive method to use. 48 patients [21%] had decided on contraception and 13 patients [5.8%] were not willing to answer the question. Out of 48 patients who decided on contraception, more than 50% underwent abdominal puerperal sterilization before discharge from the hospital. 20 mothers (7.3%) decided to use temporary contraception. So proper antenatal teaching about the importance of spacing and the available family planning options are essential to improve the acceptance of temporary contraceptive usage.

The secondary outcome is to see the relation between the critical events with the sociodemographic variables. Most of the critical events had no relationship with sociodemographic variables except the wound concerns with booking status. Un booked patients are having 3.7 times risk of having more wound infection comparatively with booked patients. The P value is 0.009, but the un booked patient numbers are less. Rest of the events for mother as well as baby has no relation with sociodemographic variables regarding their frequency.

The PI found during the active as well as passive calling, most of the mothers were highly satisfied and they were thankful to the institution for providing the easy availability of clinical advice.

CONCLUSION

- Most of the critical events (Maternal and Neonatal concerns) are occurring in the second week for mothers as well as for babies. So, the mother-baby pair can have continued health care support till 2nd week of postpartum in addition to visit to a postnatal clinic at 6th week of postpartum.
- Critical events for mothers during our study period are wound concerns, breast feeding concerns, urinary symptoms and excessive bleeding per vaginum.
- Critical events for baby are common cold, excessive crying, discharge from the umbilicus and loose stools.
- From the 2nd week of postpartum the incidence of critical events is reduced to more than half by the end of the 4th week for mother and baby pair.
- The awareness on temporary contraception are low. This should be strengthened by antenatal and postnatal education.
- 99% of mothers follow the advice on taking Iron supplementation and exclusive breast feeding.

LIMITATIONS

- Sample size is not reached during the study time.
- Critical events were not followed up. Further studies are needed to follow the reported critical events for confirming the diagnosis and assessing the magnitude of the same.
- We cannot draw recommendations based on the observed concerns without diagnosing the same.
- Mother's feedback of this telephonic support from all patients were not documented at 6th week of postpartum. Future studies should include mother's feedback on this telephonic support.

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ANNEXURES

ABBREVIATIONS

PPH- Postpartum hemorrhage

DVT- Deep vein thrombosis

VTE- Venous thromboembolism

GDM- Gestational diabetes mellitus

UTI- Urinary tract infection

LSCS- Lower segment Cesarean section

URI- Upper respiratory tract infection

MRSA- Methicillin resistance staph aureus

SMS- Short message service

USA- United states of America

MSAF- Meconium stained amniotic fluid

CT- Computerized Tomography

MRI- Magnetic Resonance Imaging

ACOG- American college of Obstetrics and Gynaecology

WHO- World Health Organization

NICU- Neonatal Intensive Care Unit

OHA- Oral Hypoglycemic Agents

ICU- Intensive Care Unit

CMCH- Christian Medical college Hospital

NFHS- National Family Health survey

CU-T- Copper T



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Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

January 25, 2019

Dr. Parisuddharao Koduri,
Department of OG - 4,
Christian Medical College,
Vellore - 632 002.

Sub: Fluid Research Grant: New Proposal:

A prospective study on reporting of critical events of low risk postnatal women in the postnatal period who delivered in a teaching hospital in South India through telephonic conversation.
Dr. Parisuddharao Koduri, PG registrar, OG 4 unit. Dr. Reeta Vijayaselvi, OG4 unit, Dr. Liji Sarah David, OG Unit 4, Dr. Preethi RN OG Unit 3, Dr. Hilda Yenuberi OG Unit 3, Dr. Shanu Neonatology, Mrs. Grace Rebekah, Biostatistics.

Ref: IRB Min. No. 11701 [OBSERVE] dated 03.12.2018

Dear Dr. Parisuddharao Koduri,

I enclose the following documents:-

1. Institutional Review Board approval Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr Reeta Vijayaselvi, Dept. of OG - 4, CMC, Vellore

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Ref: IRB Min. No. 11701 [OBSERVE] dated 03.12.2018

Dear Dr. Parisuddharao Koduri,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "A prospective study on reporting of critical events of low risk postnatal women in the postnatal period who delivered in a teaching hospital in South India through telephonic conversation" on December 03rd 2018.

The Committee reviewed the following documents:

1. IRB application format
2. Patient Information Sheet and Consent form (Tamil, English, Hindi, Telugu)
3. Questionnaire
4. Cvs of Drs. P Rao, Liji, Reeta, Hilda, Preethi and Shanu.
5. No. of documents 1- 5.

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on December 03rd 2018 in the New IRB Room, Bagayam, Christian Medical College, Vellore 632 004.

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Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology), Dr. Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Ratna Prabha	MBBS, MD (Pharma)	Associate Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL.	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
Dr. John Jude Prakash	MBBS, MD,	Professor, Clinical Virology, CMC, Vellore	Internal, Clinician
Dr. Rekha Pai	BSc, MSc, PhD	Associate Professor, Pathology, CMC, Vellore	Internal, Basic Medical Scientist
Mrs. Sophia V	M.Sc Nursing	Addl. Deputy Dean CMC, Vellore	Internal, Nurse
Dr. Ekta Rai	MBBS, MD MRCA	Professor, Department of Anaesthesia, CMC, Vellore	Internal, Clinician
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. Inian Samarasam	MS, FRCS, FRACS	Professor, Surgery, CMC, Vellore	Internal, Clinician

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Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Dr. Jayaprakash Muliylil	BSC, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist & Epidemiologist
Mrs. Nirmala Margaret	MSc Nursing	Addl. Deputy Nursing Superintendent, College of Nursing, CMC, Vellore	Internal, Nurse
Dr. Asha Solomon	MSc Nursing	Associate Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. Santhanam Sridhar	MBBS, DCH, DNB	Professor, Neonatology, CMC, Vellore	Internal, Clinician
Dr. Ajith Sivadasan	MD, DM	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician
Mrs. Sheela Durai	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. Winsely Rose	Dr. Winsely Rose	Dr. Winsely Rose	Dr. Winsely Rose
MBBS, MD (Paed)	MBBS, MD (Paed)	MBBS, MD (Paed)	MBBS, MD (Paed)
Dr. Shyam Kumar NK	MBBS, DMRD, DNB, FRCR, FRANZCR	Professor, Radiology, CMC, Vellore	Internal, Clinician
Dr. Vivek Mathew	MD (Gen. Med.) DM (Neuro) Dip. NB (Neuro)	Professor, Neurology, CMC, Vellore	Internal, Clinician
Ms. Grace Rebekah	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Barney Isaac	MBBS, DNB (Respiratory Diseases)	Associate Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician

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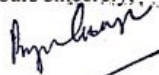
We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "A prospective study on reporting of critical events of low risk postnatal women in the postnatal period who delivered in a teaching hospital in South India through telephonic conversation" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 10,000/- INR (Rupees Ten Thousand Only) will be granted for 12 Months.

Yours sincerely,


Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

IRB Min. No. 11701 [OBSERVE] dated 03.12.2018



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INFORMATION SHEET

Department of Obstetrics and Gynaecology unit 4, Christian medical college, Vellore.

Title of Research: A prospective study on reporting of critical events of low risk postnatal women in the postnatal period who delivered in a teaching hospital in South India through telephonic conversation.

Information for the postnatal mother on discharge for a safe postnatal period:

The post delivery period especially six weeks from delivery is when changes that occurred during the nine months of pregnancy normalize. We are providing you with an information sheet to alert you of the possible complications that could occur during this period which need immediate medical assistance. The post delivery period is safe most of the time. However, symptoms in the mother that need immediate admission to the Emergency Department are as follows:

1. Any difficulty in passing urine
2. Sudden and profuse vaginal blood loss.
3. Fever with or without shivering
4. Severe Headache with Visual disturbances.
5. Pain and swelling with redness in one leg.
6. Breathlessness.

LIFE THREATENING CONDITION FOR THE BABY

1. Fever

2. Jaundice beyond 7 days of birth
3. Abdominal distension
4. Poor feeding
5. Lethargy

If your baby has any of these above-mentioned symptoms, you have to bring the baby immediately to CMC pediatric causality for evaluation and treatment.

BREAST FEEDING

1. Practice unrestricted breastfeeding frequency and duration
2. Formula milk should not be given to breastfed babies unless medically indicated
3. Wear a well-fitting bra that does not restrict your breasts
4. If the nipples are painful or cracked, it is probably due to incorrect attachment. Practice correct attachment of baby's mouth to the breast.
5. Skin-to-skin contact or massaging a baby's feet should be used to wake the sleepy baby

CONTRACEPTION

1. Can resume normal sexual contact after 6 weeks postpartum and contraception should be practiced from 2 months postpartum onwards
2. Ovulation can occur as early as 6 weeks
3. Unprotected sex in the postpartum period can end up in pregnancy
4. You can use progesterone only pill or long acting contraceptives like DMPA injection or copper T
5. If you have completed the childbirth you can plan permanent contraception like sterilization

PERSONAL HYGIENE

1. Take bath everyday
2. Keep the perineal area clean.
3. Change the perineal pads often (every 4 HRS)
3. The wound (both the perineal and LSCS) should be cleaned with clean water and wiped with clean cloth and kept dry.
4. Any experience of perineal pain, pain in the suture site, discharge from the wound, discomfort or stinging or offensive odor suggest non healing of the wound

POSTNATAL NUTRITION:

1. Drink 2-3 liter of fluid every day
2. Take balanced diet
3. Diet with high fiber content like fruits and vegetables facilitate the free movement of bowel
4. Increase the protein content of the diet to improve milk secretion

NEONATAL CARE

1. Healthy babies should have normal color for their ethnicity, maintain a stable body temperature, and pass urine and stools at regular intervals. They initiate feeds, suck well on the breast (or bottle) and settle between feeds. They are not excessively irritable, tense, sleepy or floppy
2. The umbilical cord of the baby should be kept clean and dry.
3. Incessant cry of the baby need evaluation. Incessant crying due to colic should not be treated with anticolitic medications.
4. Temperature of 38-degree Celsius needs urgent attention by a doctor
5. Vitamin drops, additional digestive syrups or native medicines are not needed for the baby

Department of Obstetrics and Gynaecology, unit 4. Christian Medical College, Vellore.

First 6 weeks after delivery is called as postnatal period. During postnatal period, mothers can have problems like excessive bleeding per vagina, sour nipple, breast infection, perineal wound or cesarean wound infection, fever with foul smelling vaginal discharge and depression. Problems for baby are weight loss, jaundice, poor feeding and fever for which you may seek advice from doctors. It is an opportunity for you to have continued care throughout the postnatal period if you participate in the study

The aim of the study is to identify the health concerns of the mother regarding the health of mother and baby during postnatal period. This study also identifies the satisfaction level of the women on telephonic conversation in addressing their concerns.

If you take part what will you have to do?

If you are willing to participate in the study, you will be given a contact phone number in which you can call the doctor between 9am to 7pm if you have any health concerns for you or for your baby till next 6 weeks. If we missed your call when you are calling, you will be called back within 4-6hrs. You will be contacted by the doctor by phone at 2nd week and 4th week, with a set of pre prepared questions regarding your and your baby's health. If we found any major problem, we will advise you to seek the medical advice in CMC as early as possible. You will be asked to fill a feedback when you come for your postnatal checkup.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you. We are unable to provide any monetary compensation, however.

Will you have to pay for the study?

No need for you to pay money when you seek the advice. You can be in touch with doctor if you have any health concern. You can seek advice if needed.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal, but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any queries regarding the health or the study, you can contact us

Dr. Parisuddharao, Principle investigator, mobile number 7635035421, Time 9 AM TO 7 PM on all days

DrReeta vijayaselvi, Guide, OG 4 Unit, CMC Vellore.04162286185.

Department of Obstetrics and Gynaecology unit 4, Christian medical college, Vellore.

Informed Consent form to participate in a research study

- **Title of Research:** A prospective study on reporting of critical events of low risk postnatal women in the postnatal period who delivered in a teaching hospital in South India through telephonic conversation. (POSTNATAL TELEPHONIC SUPPORTIVE STUDY)

Study Number: _____

Subject's Initials: _____ **Subject's Name:**

Husband name:

Date of Birth / Age: _____

(Subject)

(I) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.

[]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. []

(iii) I understand that, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. []

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). []

(v) I agree to take part in the above study. []

(vi) I am aware of the Audio-visual recording of the Informed Consent. []

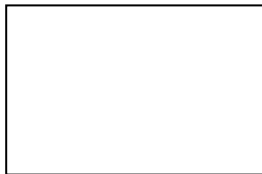
Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: ____/____/____

Signatory's Name: _____

Signature:

Or



Husband's name:

Signature of the husband:

Signature of the Investigator: _____

Date: ____/____/____

Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

Date: ____/____/____

Name & Address of the Witness: _____

Department of Obstetrics and Gynaecology unit 4, Christian medical College, Vellore-
Information on socio demographic clinical variables

Name

Hospital number

Date of enrollment:

Husband name:

Phone number 1:

Phone number 2:

Place of residence

Socio economic status (low/middle/upper)

Family income

Occupation of patient and husband

Educational status of patient and husband

Type of family (Nuclear/ joint)

Booking status (Booked /Un booked)

Age of the patient

Date of delivery

Parity

Mode of delivery
weight

Sex of the baby

Birth

Small for gestational age (<2.5kg)

Day of discharge

Postnatal telephonic supportive study, Department of obstetrics and Gynaecology unit 4, Christian medical college, Vellore- Active communication Questionnaire.

Patient name:

Hospital number:

Date:

Date of calling:

1.

2.

Duration of calling:

1.

2.

**Mode of delivery
suction cup**

Normal

LSCS

Forceps

Have you had any emergencies for you needing hospital visit in the past weeks (Yes/No)?

If answer is yes, then what is the reason?

Have your baby had any emergencies for your baby needing hospital visit in the past weeks (Yes/No)

If answer is yes, then what is the reason?

1. Nutrition: A) Are you taking Iron/Calcium tablets regularly? (Yes/No)

If answer is NO, what is the reason?

B). Are you taking balanced diet (vegetables, fruits, high protein diet) (Yes/No)?

If answer is NO, what is the reason?

C) Are you are taking adequate water 3lt per day (Yes/No)

If answer is NO, what is the reason?

2. Breast feeding: A] Are you giving exclusive breast feeding (Yes/NO)

If answer is NO, what is the reason?

B] Any other problem with feeding (Yes/No)

If answer is YES, then what is the problem?

3. Wound: A) Whether your wound has healed (Yes/No)

B] Any discharge? (Yes/No)

C] Any swelling (Yes/No)

D) Are you having abnormal discharge with fever (Yes/No)

7. Bowel and micturition: A) Are you having problems while passing urine (Dysuria, increased frequency ETC}

8. Emotional wellbeing of the mother:

A). Are you staying in mothers place (Yes/NO)?

If answer is No, where are you placed?

B). Are you able to cope up (Yes/No)?

If answer is No, what is the likely reason?

C). Are you getting enough support from the family (Yes/No)?

If answer is No, what is the likely reason?

D) Is there any other problem (Yes/No)

If answer is Yes, Specify about it?

9. Baby:

A) Is your baby is active (Yes/No)

B) Whether your baby is gaining weight clinically (Yes/No)

C) Is your baby is looking yellow (Yes/No)

10. Contraception: Have you decided on birth spacing plan/permanent sterilization plan (Yes/No)

If the answer is yes, then what is the plan?

Any other issues:

ADVICE GIVEN ON:

1.

2

3

**Department of obstetrics and Gynaecology unit 4, Christian medical college,
Vellore- Postnatal telephonic supportive Study questionnaire for passive
communication**

Name

Hospital number

Date of calling

Duration of call

Critical event raised by

Mother/ husband/ family member)

Critical event

for mother/ baby/ both mother and baby

Critical event:

1.

2.

3.

Advice given:

1.

2.

3.

RAJAVALLU	509911H	05.06.2019	9003556777, 9443446537	20.06.2019	28.06.2019	P2L2	NVD	BOY	2.48KG
SATHIYA	174916B	05.06.2019	9597128640, 8939637014	20.06.2019	28.06.2019	P1L1	LOW FORCEPS	BOY	2.40KG
PAVANA KUMARI	837160F	05.06.2019	8106615813, 9603359450	20.06.2019	28.06.2019	P2L2	LSCS	BOY	3.00KG
JYOTHEESWARI	498960H	05.06.2019	9063177432, 7036871598	20.06.2019	28.06.2019	P1L1	NVD	GIRL	3.10KG
MAHALAKSHMI	411114H	06.06.2019	9751512157,	20.06.2019	28.06.2019	P2L2	NVD	BOY	3.23KG
AARIFA BEGUM	991031G	06.06.2019	7845471344, 8148324276	20.06.2019	28.06.2019	P2L2	NVD	BOY	3.15KG
KALAIVANI	427051H	06.06.2019	9600597538, 9047150959	20.06.2019	28.06.2019	P1L1	SUCTION CUP	GIRL	3.58KG
RENUKA	399918H	06.06.2019	9092428830, 9942451988	20.06.2019	28.06.2019	P1L1	NVD	BOY	3.70KG
PREMA	752016G	06.06.2019	9566795678, 9629580017	20.06.2019	28.06.2019	P2L2	NVD	GIRL	2.98KG
DEEPA S	512843H	06.06.2019	9488828912, 7090144972	20.06.2019	28.06.2019	P1L1	NVD	BOY	2.42KG
VIDHYA	280611G	28.05.2019	9384495526, 9590971807	10.06.2019	24.06.2019	P3L3	NVD	GIRL	2.82KG
TAMILSELVI	628078H	23.05.2019	9500416499, 8608542016	10.06.2019	24.06.2019	P1L1	SUCTION CUP	BOY	3.28KG
CHANDINI	995521G	28.05.2019	9791226756, 9840527612	10.06.2019	24.06.2019	P2L2	LSCS	GIRL	3.44KG
ARTHI	516338H	23.05.2019	9042104525, 7845292873	10.06.2019	24.06.2019	P1L1	NVD	GIRL	2.70KG
RAMYA	775670G	03.06.2019	9600732483, 9385449008	10.06.2019	24.06.2019	P2L2	LSCS	BOY	3.16KG
BHAVANI	961648G	03.06.2019	9952388656, 9894813933	10.06.2019	24.06.2019	P2L2	NVD	BOY	2.98KG
BAKYA LAKSHMI	531345H	03.06.2019	9445453277, 8610797112	10.06.2019	24.06.2019	P1L1	LSCS	BOY	3.42KG
GOWTHAM	521483G	03.06.2019	8940712520, 9943545393	10.06.2019	24.06.2019	P2L2	LSCS	GIRL	3.06KG
DHANALAKSHMI	447893H	03.06.2019	8074068734, 9566826283	10.06.2019	24.06.2019	P1L1	LOW FORCEPS	GIRL	2.48KG
HEMA MAJINI	419675H	03.06.2019	7200951063, 9944317870	10.06.2019	24.06.2019	P2L2	NVD	BOY	3.18KG
SARASWATHY P	960054G	10.06.2019	9894637378,	24.06.2019	5.07.2019	P2L2	LSCS	GIRL	2.66KG
SAJIDA BEGUM	605199H	10.06.2019	9003386190, 9952566190	24.06.2019	05.07.2019	P1L1	NVD	BOY	2.48KG
AMSAVENI	559442H	11.06.2019	9597236567, 8148898778	24.06.2019	05.07.2019	P1L1	OUTLET FORCEPS	BOY	3.78KG
DURGAM NIREESHA	570901H	11.06.2019	9490279245, 6304336810	27.06.2019	05.07.2019	P1L1	SUCTION CUP	BOY	3.01KG
PRIYADHARSHINI	610545H	11.06.2019	8919785345, 6305317118	27.06.2019	05.07.2019	P1L1	LSCS	BOY	3.16KG
SATHIYA	619474H	11.06.2019	9994940890, 9994323036	27.06.2019	05.07.2019	P3L3	NVD	GIRL	2.40KG
GOWTHAMI	717893G	13.06.2019	9738140424, 8310984422	27.06.2019	05.07.2019	P2L2	NVD	GIRL	3.70KG
BAKYALAKSHMI	053734H	13.06.2019	8531883918, 9842108480	27.06.2019	05.07.2019	P2L2	LSCS	GIRL	2.64KG
KAVITHA G	186778H	13.06.2019	9043910974,	27.06.2019	05.07.2019	P1L1	OUTLET FORCEPS	GIRL	2.6KG
NEERAJA B	427441H	13.06.2019	8686341811, 9398883461	27.06.2019	05.07.2019	P1L1	LOW FORCEPS	GIRL	3.12KG
BHAVANI	467932H	18.06.2019	9047935457, 9585399496	29.06.2019	10.07.2019	P2L2	LSCS	GIRL	2.7KG
REVATHI	535543H	18.06.2019	9087935283, 9884913223	29.06.2019	10.07.2019	P2L2	LSCS	GIRL	2.82KG
RAMYA	504058H	19.06.2019	7904559505, 9789321678	29.06.2019	10.07.2019	P1L1	LOW FORCEPS	BOY	3.29KG
PREETHI	522135H	19.06.2019	9087606377, 9003518187	29.06.2019	10.07.2019	P1L1	NVD	GIRL	2.58KG
GOMATHI N	631279D	19.06.2019	8056708128,	29.06.2019	10.07.2019	P2L2	NVD+ST	GIRL	2.40KG
NANDHINI G	115660G	20.06.2019	9629525399, 9629855099	01.07.2019	14.07.2019	P2L2	NVD	BOY	3.00KG
HEMAPRIYA K	508874H	20.06.2019	9944216925, 8124044482	01.07.2019	14.07.2019	P1L1	NVD	BOY	2.78KG
RADHIKA M	605281H	20.06.2019	9944587708, 9585005194	01.07.2019	14.07.2019	P1L1	LOW FORCEPS	GIRL	3.00KG
KALPANA	848329F	21.06.2019	9159783463, 9843981961	01.07.2019	14.07.2019	P3L3	LSCS	BOY	3.42KG
VINAYAGASELVI	934520D	21.06.2019	9751564205, 8940019205	01.07.2019	14.07.2019	P2L2	NVD	BOY	2.80KG
NANDHINI S	428906G	21.06.2019	9600685046, 9994085708	01.07.2019	14.07.2019	P1L1	NVD	GIRL	3.00KG
SANTHA KUMARI	445679H	21.06.2019	9908754669, 955007329	01.07.2019	14.07.2019	P2L2	NVD	BOY	2.90KG
DHARANI C	616012H	21.06.2019	9751808711, 9585281415	01.07.2019	14.07.2019	P1L1	SUCTION CUP	BOY	2.80KG
NARMADA	470627H	21.06.2019	9901801318, 8098587472	01.07.2019	14.07.2019	P1L1	NVD	BOY	2.59KG
SK KHUMA PARVEEN	057336G	22.06.2019	9515713129,	05.07.2019	28.07.2019	P1L1	NVD	BOY	2.70KG
ANBARASI	248421G	22.06.2019	9159052100, 6383323387	05.07.2019	28.07.2019	P2L2	NVD	BOY	3.00KG
RANJITHA M R	600567H	22.06.2019	7397693671, 7845121367	05.07.2019	28.07.2019	P1L1	NVD	BOY	2.80KG

Passive calling data

