Protocol on Effects of breast caps on breast engorgement among postnatal mother.

ABSTRACT

Breast Engorgement as the physiologic process of body in postnatal mothers following birth, having sign and symptoms of painful swelling of the breast combine with sudden increase in milk volume. Resulting in Lymphatic and vascular blockage or obstruction, interstitial oedema, if not treated complications of nipples and breast arise. Pharmacological and alternative methods are available to manage. Hot and Cold compresses showed overall benefits without having side effects. but seeing the shape and contour of breast, hot water bag being flat does not fit to breast to give comfort to mother and also its rubber material cause irritation and allergic. The objectives of this study are development of Breast Caps and study its effectiveness for management of Breast Engorgement. In this study Qualitative research approach, Intervention study design, simple random sampling techniques is used to allocate 125 samples in experimental and 100 in control group. Experimental group will receive application of Breast Caps having temperature 43-46^{0}F, 10 -15 minutes, thrice a day for three consecutive days and control group receive application of Hot Water Bag. Primary outcome will be development of Breast Caps and secondary outcome will be reduction in sign and symptoms of breast engorgement and pain level assess by using 6point self-rating breast engorgement scale(SPES) and visual analogue pain scale (VAS). Ethical approval was obtained by IEC,DMIMS(DU)/IEC/2020-21/8387.The study result and data will be disseminated in peer-review publication. The study result will be concluded that Breast Caps can be comfortably and effectively used for management the condition of Breast Engorgement in postnatal mothers in hospitals and also in home settings.

KEY WORDS: Breast Engorgement, Breast Caps, Hot Water Bag, Breast Complication, Postnatal mother.

INTRODUCTION:

Breast Engorgement is a physiologic condition or state of body in delivered mothers following birth characterized by having swelling and pain in breast combine with the sudden rise in milk volume associated with the sign and symptoms of lymphatic and vascular blockage and interstitial oedema during first week after birth.[1] Statistical evidence shows the incidence rate of breast engorgement throughout the world is 1:8000, and in India it is 1:6500, If engorgement left untreated it can lead to potentially serious issues like ,a Poor Latch ,a Low Breast Milk Supply, having the effects on new born showing Poor Weight Gain, because of not able to get enough breast milk, Other effects may be Forceful Flow of Breast Milk which may be difficult for baby during breast feeding causing baby to gag, choke, and swallow excessive amounts of air, Difficulty in latching thus result in early refusal of breast feeding. On other hand Breast early weaning due to problem of sore nipples, blebs, mastitis and plugged milk ducts. [2]

Findings of study done in Kamala Nehru Memorial Hospital Allahabad, India to know the problems and complications of breast and nipples in early postnatal period were found to be breast engorgement 43.33%, cracked nipples 15.83 %, retracted nipples 10%, cracked and sore nipples 8.33% [3]

In decades of years, for management of breast engorgement and its related problems, many studies were done In previous studies ultrasound therapy with conventional therapy on breast

engorgement is compatively done to find the effectiveness of ultrasound therapy in immediate post-partum mothers**.** Visual Analogue Scale (VAS), and Six-point engorgement scale (SPES) were used to measure the outcome. The pre-treatment and post-treatment values of outcome measures were compared which showed that VAS SPES scores was statistically significant on 2nd and 3rd day post-intervention. Pre-intervention and post-intervention at 4th day were statistically significant. The study concluded that ultrasound therapy added with conventional therapy helps to reduce the level of hardness and tenderness of breast along with reduction in pain level. [4]

Some studies used Hot Water Bag and Cold Cabbage Leaves are used to give hot and cold compress, which was time consuming and cause discomfort.[5]Other studies used Dazen (an anti-inflammatory drug)and Hollyhock(Althaea officinal).[6]Manually massage and pump are also used.[7] Education on Specific massage and hand expression techniques given to mothers in outpatient department for management of breast engorgement which was found helpful.[8]Results shows that at the Post Discharge new born visit majority of mothers came with the problems of breast engorgement. Other study used two methods to find out the effects of scraping (Gua - Sha) therapy in experimental group and massage and heating is given to control group. Gha Sha therapy shows as a evidence to reduce the breast engorgement. [9] A randomized controlled trial was done to study the outcome of kinesio taping (KT) and manual lymphatic drainage (MLD) on postnatal on pain severity, breast engorgement, and milk volume. Participants randomly assigned to the KT, MLD, and control group. Post intervention result ware compared which shows that The MLD group had significant reductions in pain and breast engorgement compared with the control and KT group. Milk volume increased among three groups, but the change in the MLD group was higher than in the KT and control groups [10]

Herbal and hot compresses are studied for maternal breast engorgement. Pre and post analysis of pain was done using visual analogue scale. The pain reduction after herbal compresses was found to be greater than with the hot compresses. [11] Alma Alfatir hot compress was also used to manage in reducing the condition of breast engorgement [12] Hot Ginger Compress was also used to reduce breast engorgement in lactating mothers which was found to be effective. [13]

Most common drugs used for management of breast engorgement are Bromocriptin and uterotonics (Oxytocin) which report showing the effects on Primitive Neonatal Reflexes. [14] Stopping breastfeeding for physical reasons such as pain or difficulty. These findings suggest that injection of prophylactic uteronics may reduce breastfeeding duration, but not initiation of breast feeding. [15] Study on multidisciplinary approach is done for management of breast engorgement. In this case the participant was readmitted on third day after discharge presenting with the problems of feedback inhibition of lactation. Participants received breast feeding counselling, family- cantered care and was assist in pumping the breast milk, also anti-inflammatory drug is added in the treatment and low dose of prolactin inhibitor given. At postpartum day 14 participant was discharge with reduction in breast engorgement and re-establishment of milk flow. [16]

Prevalently included studies used pharmacological as well as non-pharmacological methods to reduce from severity of breast engorgement. Some studies are effective without having side effects, some are found to be not comfortable, time consuming and does not shows desirable effects. Thus there is a need to do more studies for evidence.

Rational: Indrani D, Sowmya MV (2019) found the Prevalence of Breast Engorgement among Lactating Mothers were 65|% - prevalence were 65%-]75% [17]in rural population. In majority of studies are comparatively done using hot and cold compresses.

In most of studies, warm compress is used which shows good results to relief from pain and reduced breast engorgement signs and symptoms.

Warm compress also show effect to easy express of breast milk and no need to give medication. Thus one should not have to concerned about side effects while giving warm compress. Other physiological effects of application of heat is vasodilatation, resulting increase capillary permeability and cellular metabolism collectively cause sedative effect. Oxygen, nutrients, antibodies and leukocytes are supplied to affected or targeted area. Mostly in hospital and home settings Hot Water bag is used to give the hot compresses which does not effectively fits the shape of the breast causing discomfort and also sometimes allergic to rubber material is reported. Thus taking consideration of comfort and effective effect researcher tries to develop and study the effectiveness of breast caps for management of breast engorgement among postnatal mothers and reducing the problems associated with it

AIM: To develop and evaluate the effectiveness of Breast Caps {BC} for management of breast engorgement among postnatal mothers in selected rural hospitals

OBJECTIVES:

Phase -1

- To design, develop and validate Breast Caps {BC} for management of breast engorgement among postnatal mothers in selected rural hospitals.

Phase -2

- To assess the degree of breast engorgement and level of pain in postnatal mothers of experimental and control group
- To study the effectiveness of Breast Caps {BC} for management of breast engorgement.
- To know the level of self – satisfaction among postnatal mothers using Breast Caps (BC) for management of breast engorgement in selected rural hospitals.

METHODOLOGY:

Qualitative research approach and interventional research design, Post-natal mothers admitted in postnatal wards in selected rural hospitals of Wardha, which are identified with the problem of breast engorgement 125 in experimental which will receive the application of Breast Caps (BC)and 100 in control group which will receive Hot Water Bag (HWB). Samples will be selected using Simple random sampling by lottery method. Investigator will enrol participants, and assign participants to interventions.

Blinding (masking): Single blinding

Intervention:

Six Point Self-Rated Engorgement Scale (SPES) will be used to assess the degree of Breast Engorgement and level of pain will be assess by using Visual Analogue Scale (VAS)[17]before every time of intervention. Self-fitting Breast Caps {BC}hot compress will range between43°C and 45°C, will give to the mothers for10-15 minutes, thrice a day for three continuous days will to experimental group before breast feeding and Hot Water Bag{HWB}to control group. Breast feeding is continued. Prescribed drug in postnatal period will be continued. After three days of treatment, the outcome will be measure by using Six Point Self-Rated Engorgement Scale (SPES) and Visual Analogue Scale (VAS) in both groups. Fig no- 1

Criteria for discontinuing the application of Hot Caps if patient wants to withdraw from treatment, filling of uncomfortable

Inclusion criteria:
Postnatal mothers identified breast engorgement symptoms and pain, who are ready to participate.

Exclusion criteria:
Postnatal mothers having nipple problems such as nipple sore, nipple cracks, inverted nipple and other complications. Those who are seriously ill.

Sample size:
Based on available literature of related researches, sample size is calculated using formula of desired error of margin.

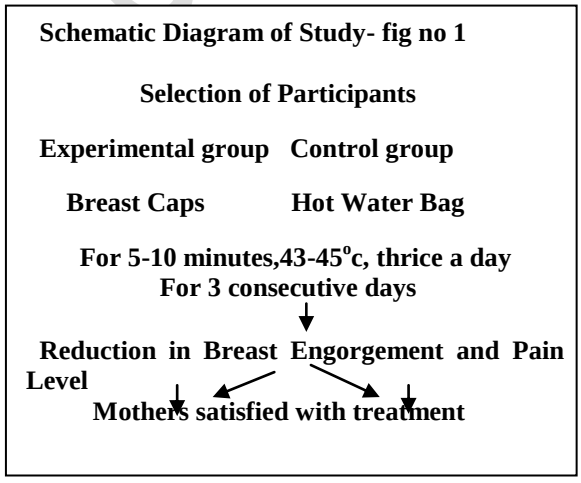
$$n = \frac{Z\alpha/2^2.p.(1-P)}{d^2}$$

where d^2
Zα /2 isthe level of significance at 5% i.e.95%
Confidence interval =1.96
p =Prevalence of Breast Engorgement = 20% = 0.20
d = Desired error of margin = 7% = 0.07

$$n = \frac{1.96^2 x\ 0.20\ x\ (1-0.20)}{0.07^2} = 125.44$$

Experimental group n = 125patients needed in the study
Control group n = 100 patients

Primary Outcome: Development of Breast Caps.
Secondary Outcome: Evaluating the effectiveness of Breast Caps for management of breast engorgement, Mothers effectively feeding their babies and Self Satisfaction of mothers with treatment.



Data collection:
1- Demographic Sheet
2- Six Point Self-Rated Engorgement Scale (SPES) to assess breast engorgement.
3- Visual Analogue Scale (VAS) to assess pain level.
4- Likert scale to assess mother's satisfaction level with treatment of Breast Caps.

ETHICS AND DISSEMINATION

IEC,DMIMS(DU)/IEC/2020-21/8387.The study result and data will be disseminated in peer-review publication.
Consent or assent: Investigator will obtain informed written consent or assent from study participants.
Confidentiality: Confidentiality will maintain related Personal information about enrolled participants before, during, and after the trial.
Data management: By using appropriate descriptive and statistical methods (SPSS and parametric and non-parametric test)
Access to data: Assess to the final trial dataset will be handle by investigator and limit the access for disclosure of contractual agreements.
Dissemination policy: Result will publish in publication.

RESULT AND DISSCUSSTION

Development of Breast Caps will assess by mother's satisfaction level. Effectiveness of the Breast Caps will show reduction in Breast Engorgement symptoms such Swelling, congestion which will be assessed by Six Point Breast Engorgement Scale (SPES) and reduction in pain level assessed by Visual Analogue Scale (VAS)
Breast Caps will be effectively used in management and control the symptoms of Breast Engorgement in postnatal mothers in hospitals and home setting

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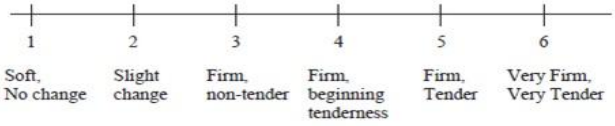
ANNEXURES :

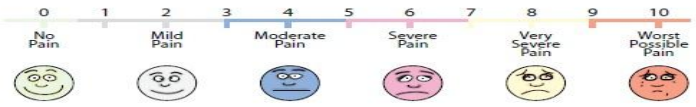
1. Six Point Self-rated Engorgement Scale (SPES) developed by Pamela D. Hill, RN, and Sharron S. humenick RN and Visual Analogue Scale (VAS) developed by Donna Wong and Connie Baker.
Participants will rate degree of Breast engorgement on SPES



Scale from 1 to 6

1- being soft, no change
2- Being slight change
3- Being firm, non-tender
4- Being firm, beginning tenderness
5- Being firm, tender
6- Being very firm, very tender, [Measure of 3 which is firm and non-tender are included as a threshold for subjective rating]

2. Participants will rate Level of Pain on VAS



0- Being no pain
1-3 Being mild pain
3-5 Being moderate pain
5-7 Being sever pain
7-9 Being very severe pain
9-10 Being worst possible pain [10 being the worst possible pain, 5moderate pain, 0 no pain]. The threshold for pain measure 3points or more above baseline.