Title

COMPARISON OF OUTCOME BETWEEN GRISOTTI FLAP VERSUS REVERSE MIRROR GRISOTTI FLAP FOR CENTRAL QUADRANT BREAST TUMORS

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INTRODUCTION:

Breast cancer amongst women is the most common cancer and the second leading cause of deaths related to cancer worldwide.[6] Its incidence is rising by 1% annually during 2012–2021, largely confined to localized-stage and hormone receptor-positive disease.[1] A steeper increase in women < 50 years (1.4% annual) versus ≥50 years (0.7%) overall was significant only among White women. African/Pacific Islander women had the fastest increase in both age groups (2.7% for women <50 years and 2.5% for women ≥ 50 years per year)[1]. Hence, young Asian ,American/Pacific Islander women had the second lowest rate in 2000 (57.4 per 100,000) but the highest rate in 2021 (86.3 per 100,000). [1]

In a multitude of developed and emerging countries, including Pakistan, breast cancer is a cause of significant morbidity and mortality.[1,2] The average age of developing a breast cancer among white American women is 61 years, however the average age for Pakistani women is 51.4 years.[2]

In the past, mastectomy was treatment of choice for any stage of breast cancer.[9] However newer advancements resulting in early diagnosis, providing advancved systemic therapies and easy availability of radiotherapy facilities have paved the paths for breast conservations.[7,9] Sometimes the size and location of the tumor leads to undesired aesthetic results which can be encountered when attempting resections with safe margins. The major part of the aesthetic problem after breast conservation surgery is due to large glandular defects and scars contractures.[15] This is where oncoplastic techniques are used for the repair of resulting glandular defects without compromising the oncological outcomes.[7,9,15]

Breast oncoplastic surgery, integrating oncologic and plastic surgery principles, is increasingly prevailing in developed as well as developing countries. The technique involves precise and thorough planning of incisions,excisions, glandular reshaping and nipple areolar complex (NAC) repositioning for improved and symmetrical aesthetic

outcomes.[3] Oncoplastic breast surgery has hence become the standard of care in breast cancer owing to its feasibility,advances and oncological safety .[5]

Among the different quadrant tumours, centrally located breast tumours (CLBT) account for about 5–20% of all breast cancer cases.[7,9] Because of their location CLBT pose special oncological and aesthetic concerns. Selecting an optimal surgical approach for CLBT remains debated till date, reflecting the complexity of balancing oncologic principles with aesthetic outcomes and local control.[3] The resection of NAC is almost always necessary in central quadrant tumours and aesthetic outcomes are mostly poor if only a standard breast conservative therapy is performed.[14]

Oncoplastic approaches for centrally located breast tumours may include Grisotti flap, reverse mirror grisotti flap, latissimus dorsi flap, inferior pedicle flap, Melon slice, and round block techniques[16]. For centrally located breast tumours Grisotti flap technique has a short learning curve, quick to perform, with a low complication rate, satisfactory cosmetic outcome and no loss of body image in the post-operative period making it a more physiological procedure.[7,13] The oncologic outcome of oncoplastic breast conservation was shown to be comparable to the classical mastectomy in cases of central breast tumors [10]. The Grisotti technique consists of excising central quadrant breast tumor alongwith nipple areolar complex and mobilizing a dermo-glandular flap which is de-epithelized, rotated and advanced based on inferior and lateral pedicle in order to fill the glandular defect and reshape the breast, recreating a neo-areola.[8,9] Grisotti flap is a partial mastectomy and an immediate volume replacement technique[10]

The Grisotti flap technique demonstrated superior patient satisfaction alongwith aesthetic and psycho-social outcomes while maintaining oncological safety that is comparable to that of mastectomy.Hence Grisotti flap technique is a standard alternative to mastectomy, particularly in patients prioritizing aesthetic outcomes**.** [4,6] Advances in oncoplastics have devised the modification of this original technique which involves the utilizing other vascular pedicles for the dermoglandular advancement and rotation.[9]

A reverse-mirror Grisotti flap, also known as a Reverse-Bay of Bengal modification, is a variation of the Grisotti flap technique used in breast cancer surgery. It is designed to reconstruct defects in the central breast quadrant after a breast conservation surgery. This modification involves re-orienting the flap medially where it is dependent mainly on the perforators of internal mammary artery for blood supply, potentially offering better aesthetic results and more versatile and robust blood supply. The Grisotti flap, despite its well known utility, has limitations, particularly in patients with non-ptotic breasts, where it may lead to fullness laterally and suboptimal cosmesis, the Reverse Bay of Bengal modification of the Grisotti flap is designed to address these limitations by preserving chest wall perforators and avoiding excessive lateral buldging.[11] This technique hence offers a more cosmetic alternative for patients with central quadrant tumors requiring nipple-areola complex (NAC) excision.[11]

OBJECTIVES:

To compare the outcome between grisotti flap versus reverse mirror grisotti flap in terms of flap viability, cosmetic outcome (visual analogue scale) and seroma formation.

OPERATIONAL DEFINITIONS:

1. **Centrally located breast tumors (CLBT):**

Tumors that are completely or partially located in the projection of the areola up to the chest wall and/or within 2 cm around the areola

2. **Grisotti Flap:**

The Grisotti flap is a local rotational flap used to reconstruct defects after removing a central breast cancer, often involving the nipple-areola complex (NAC). It uses tissue from the inferior pole of the breast to fill the central defect.

3. **Reverse-Mirror Flap:**

The reverse-mirror version is a modification where the flap is flipped and reoriented, using the internal mammary vessels as the primary blood supply.

4. **Flap viability:**

Absence of necrosis of new areola formed as seen clinically at 48 hours and 7^{th} day postoperatively.

Flap viability categories:

A (None): No necrosis.

B (Color Change): Color change suggesting impaired perfusion or ischemic injury.

C (Partial Thickness): Partial thickness skin flap necrosis resulting in wound breakdown.

D (Full Thickness): Full thickness skin flap necrosis.

5. **Cosmetic outcome:**

Cosmetic outcome will be explained with VAS (visual analogue scale) by the patient. The scale will range from 0-10 with 0 being categorized as worst cosmetic outcome and 10 being categorized as best cosmetic outcome.

6. **Seroma formation:**

   Seroma formation is the visible swelling at the operative site which will be confirmed and quantified by ultrasound on 7^{th} post operative day with volume more than 20ml.

HYPOTHESIS:

There is a difference in the outcome between Grisotti versus Reverse Mirror Grisotti flap in centrally located breast cancers.

MATERIAL AND METHODS:

STUDY DESIGN: Randomised Control Trial

SETTING: SURGICAL FLOOR, MAYO HOSPITAL LAHORE.

DURATION OF STUDY: 06 months after approval of synopsis.

SAMPLE SIZE: Sample size of 106 patients (53 patients in each group) is estimated by using 95% confidence level, 10% absolute precision with expected percentage satisfaction rate in group A as 90% and in group B as 95%.

$$n = \frac{Z^2_{1-\alpha/2}\,(P_1(1-P_1) + P_2(1-P_2)}{d^2}$$

$Z_{1-\alpha/2}$ = confidence level 95% = 1.96

P_1 = population proportion A= 90% [14]

P_2 = Population proportion B = 95% [8]

d = absolute precision 10 %

SAMPLING TECHNIQUE: computer generated random table.

SAMPLE SELECTION:

Inclusion Criteria:

1. Diagnosed cases of breast cancer patients
2. Gender: Females
3. Age: 25-70 years
4. T1 (<2cm) and T2 (2-5cm) tumors with or without prior systemic therapy
5. Tumor located in the NAC or located within 2 cm of the edge of the areola

Exclusion Criteria:

1. Metastatic breast cancer
2. Inflammatory breast cancer
3. Patients not willing for post-operative radiotherapy
4. High tumour-breast ratio

DATA COLLECTION PROCEDURE:

The study approval will be taken from the Ethical Committee of the King Edward Medical University, Lahore and will be performed in accordance with the current revision of the Helsinki Declaration. Informed consent will be obtained from all individual participants with diagnosis of central quadrant breast tumors as per operational definition, and data will be collected on predesigned proforma. Patients will be divided into two groups, Grisotti flap (group A) and Reverse Mirror Grisotti Flap (group B). Patients will be recruited from OPD of Mayo hospital during the same study period.

Patients fulfilling the inclusion criteria will be randomly divided into either group. Pre-operative marking will be done in standing position. All procedures will be done under general anesthesia. Circumareolar incision will be given for excision of tumor alongwith nipple areolar complex. New areola will be marked beneath the previous nipple areolar complex and de-epithelialisation of infra-neo-areolar skin will be done . In group A, the dermoglandular flap will be raised on infero-lateral perforators of intercostal arteries and will be rotated and advanced to fill the gap . In group B, the dermoglandular flap will be raised on the medial perforators of internal mammary artery and will be rotated and advanced to fill the defect. In both groups, glandular approximation will be done with vicryl 3-0 interrupted sutures and skin will be closed with prolene 4-0 subcuticular sutures. Axillary lymph node dissection or sentinel lymph node biopsy will be done as indicated in each patient.

Post operatively flap viability will be assessed at 48 hours and on 7^{th} day. Cosmetic outcome will be assessed using visual analogue scale on 7^{th} postoperative day. Seroma formation will be assessed on 7^{th} day post-operatively.

DATA ANALYSIS PRODECURE:

All the collected data will be entered and analyzed by using Statistical Package for the Social Sciences (SPSS,25). Quantitative data (cosmetic outcome with VAS) will be expressed as mean (M) ± S.D. Independent T test will be used for comparing means for cosmetic outcome. Qualitative data (tumor size, flap viability and seroma formation) will be expressed as frequencies and percentages. Chi square (X^2) test will be used to compare between groups for qualitative data. The association between type of procedure used and clinical outcome variable will be assessed by using Odds Ratio (OR) with 95% confidence interval (CI). The P value will be considered significant if it is less than 0.05.

OUTCOME & UTILIZATION:

Breast conservation surgery is equivalent to mastectomy for early stage breast cancer patients. Central quadrant tumours can be treated with various oncoplastic techniques with a satisfactory aesthetic outcome and low morbidity. Grisotti flap and reverse mirror grisotti flap are the favourable viable surgical options for central quadrant breast tumours.

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Data Collection Proforma

Sr. #:_____Name: _____Age: _____ Gender: _____

Marital status: _____ Education status: _____
Residence: _____ Contact #: _____ ,

History of smoking: yes/no, family history of any cancer: yes/no_____ 1st degree: _____2nd degree:_____ 3rd degree:_____, Caste:_____, children:_____ Breast fed: yes/no,

Age of menarche:_____, H/O contraceptive use:_____
Consanguineous marriage: yes/no_____
Menopause: yes/no H/O alcohol use: yes/no, H/O smoking: _____
Chronic liver disease: yes/no Chronic renal failure: yes/no
Tuberculosis: yes/no Inflammatory bowel disease: yes/no
Autoimmune disease: yes/no Previously treated any cancer disease: yes/no
Breast cancer with pregnancy: yes/no
Diagnosis (histopathology) _____,
Histological grade: I_____, II_____, III_____
Receptors: ER_____PR_____Her 2 neu_____others_____
Stage_____ Chemo status_____
Surgery type_____Radiotherapy_____

Variable	**Group A (grisotti flap)**		**Group B (reverse mirror grisotti flap)**	
Flap viability (A-D)	**At 48 hours**	**On 7th post-op day**	**At 48 hours**	**On 7th post-op day**
Cosmetic outcome (visual analogue scale)				
Seroma formation On 7th post-op day	**Yes / No**		**Yes / No**	

Informed Consent Form

COMPARISON OF OUTCOME BETWEEN GRISOTTI FLAP VERSUS REVERSE MIRROR GRISOTTI FLAP FOR CENTRAL QUADRANT BREAST TUMORS.

The doctor has explained me about my disease. The research modalities required for treating my tumour have been thoroughly explained to me. As this research work requires the utilization of either grisotti or reverse mirror grisotti flap technique, therefore I allow the doctor to utilize any of these procedures on me.

I also have been informed in detail about the possible benefits and side effects of the study. I understand that I am free to withdraw from the study whenever I want to, and I have been informed that my doctors will continue to give me all possible care even after my discontinuation form the study.

Furthermore, I allow my doctor or any other person authorized by my doctor to contact me at my home or at any an address given by me whenever required. I have been assured that the information provided by me will be kept confidential and will be used for research purpose only.

Patient name:_____

NIC #:_____

Signature/thumb impression:_____

Investigator signature:_____