DOI: https://doi.org/10.4038/gmj.v30i2.8254 **Original article**

Assessment of risk factors and prevalence of complications following mastectomy and related axillary procedures

KPVR De Silva[1], JPM Kumarasinghe[1], RP Abeywickrema[1], SM Uluwitiya[1], ST Ekanayake[2], LUJ Wickramasinghe[2], M Imjad[2], AGI Lakmini[1], DAW Senevirathne[1], DGM Miyurangi[1], HP Subasinghe[1], K Jayawardana[1]

[1]*Department of Surgery, Faculty of Medicine, University of Ruhuna, Galle, Sri Lanka.*
[2]*Professorial Surgical Unit, National Hospital, Galle, Sri Lanka.*

Correspondence: Dr. Vidu Ruchira De Silva
e-mail: *vidu.ruchira@med.ruh.ac.lk*
https://orcid.org/0000-0001-5178-5117
Submitted on 22.01.2025 and accepted for publication on 30.05.2025

ABSTRACT

Introduction: Mastectomy is a common surgical intervention for breast carcinoma but is often associated with complications impacting patients' recovery and quality of life. The aim of the study was to determine the risk factors and the prevalence of complications following mastectomy and related axillary procedures among a selected group of patients in the National Hospital Galle.

Methods: A descriptive, cross-sectional study was carried out among 390 patients selected using convenient sampling method. The data were obtained from the medical records of the patients who underwent mastectomy and related axillary procedures from June 2022 to June 2024. Risk factors and prevalence of complications were evaluated using standard statistical tests.

Results: The most common complication was axillary paraesthesia (25.4%), while chronic pain syndrome was the least frequent (1.8%). Obesity, age >65 years, diabetes, and recurrence episodes were significant risk factors for complications. Surgical site infections were strongly associated with obesity [Odds Ratio (OR)=25.3], age >65 years (OR=6.86), and recurrence (OR=21.2). Seroma formation was associated diabetes (OR=4.43), obesity (OR=6.8), age >65 years (OR=6.60), and tumour recurrence (OR=2.63). Flap necrosis and lymphoedema were more common in patients with advanced age, diabetes, obesity, or recurrence (p<0.05 in all). Venous thromboembolism was associated with age >65 years (OR=7.09), diabetes (OR=6.43), hypertension (OR=7.02), and obesity (OR=13.14). Age >65 years was the primary risk factor for most complications, while gender and bronchial asthma had no effect.

Conclusions and recommendations: Heightened monitoring of older, obese, and chronically ill patients is crucial to reduce post-operative complications.

Comprehensive evaluations and tailored surgical and post-operative care for high-risk groups are recommended to improve outcomes.

Keywords: *Axillary procedures, Complications, Mastectomy, Prevalence, Risk factors.*

Introduction

Mastectomy is the surgical procedure which involves the removal of all or part of the breast (1). There are several indications for mastectomy including malignancies of the breast, Paget disease of the breast and as an option for risk reduction or prophylaxis in patients with BRCA1/ BRCA2 mutations Out of them, the most common indication for mastectomy is the breast malignancy which is the second most common cancer worldwide (3).

In Sri Lanka, breast cancer incidence is nearly 3,000 females per year. Although there are two main treatment modalities for early breast malignancies as mastectomy and breast conservative surgery, here in Sri Lanka breast conservation rates are low (4). Mastectomy is often accompanied by a range of postsurgical complications that can significantly impact patients' quality of life and recovery process. Mastectomy can result in post-operative complications such as wound infection, seroma formation, haematoma formation, lymphoedema and post mastectomy pain syndrome etc. Despite advancement in surgical techniques and post-operative care, the incidence of these complications is substantial (5).

Complications following mastectomy and related axillary procedures can be associated with numerous risk factors including age, body mass index (BMI), comorbidities, stage of the disease, recurrence of the disease, and the type of breast surgery. Therefore, understanding the risk factors and the prevalence of complications following mastectomy and related surgical procedures is vitally important for improving the surgical outcome, enhancing patient care and optimising healthcare resources. Furthermore, this would benefit in uplifting the quality of life of post mastectomy patients.

Most studies on incidence and trends of complications following mastectomy and related surgical procedures have been conducted in developed countries, while analyses of these trends and patterns in developing countries including Sri Lanka are limited (6). National Hospital Galle is the main centre with a separate cancer unit which accommodates the majority of patients undergoing mastectomy in the Southern province of Sri Lanka, but there are only a few studies that have been done on this aspect. Hence it was considered worth trying to assess the risk factors and the prevalence of the complications in patients who have undergone mastectomy and related axillary procedures, in order to facilitate the advancement in clinical practice. Thereby surgeons can better tailor their approach to minimise complications during and after mastectomy and related axillary procedures and improve the patient centered care.

The main objective of this study was to determine the risk factors and the prevalence of complications following mastectomy and related axillary procedures. Determining the incidence of complications following mastectomy and related axillary procedures, identifying the risk factors associated with complications and identifying the modifiable risk factors associated with complications were the specific objectives of this study.

Methods

This study was a descriptive, cross-sectional study, carried out in National Hospital Galle. The study population consisted of the patients who have undergone mastectomy and related axillary procedures in National Hospital Galle from June 2022 to June 2024. In the absence of previous prevalence estimate, the sample size for the study was calculated using 50% as the anticipated population proportion.

Accordingly, the required sample size was 384. The study included 390 patients who underwent mastectomy and related axillary procedures in all five surgical units in National Hospital Galle since June 2022 to June 2024, that were collected using convenient sampling method.

The data were obtained from the medical records including bed head tickets and the clinic records of the patients who underwent mastectomy and related axillary procedures. A one-month period after surgery was considered as the postoperative period for the study. We assessed haematoma, seroma, wound infection, lymphoedema, flap necrosis, venous thromboembolism, frozen shoulder, paraesthesia of axilla and chronic pain syndrome as the postoperative complications of mastectomy and related axillary procedures in this study.

Ethical clearance was obtained from the Ethics Review Committee of the Faculty of Medicine, University of Ruhuna. The data were entered into a data extraction sheet. Data was analysed using *SPSS*™ (Statistical Package for Social Sciences) version 24. As endpoints of the study, prevalence of the complications following mastectomy and related axillary procedures and risk factors associated were identified.

Results

Socio-demographic profile of sample

The study sample consisted of 390 patients who underwent mastectomy and related axillary procedures. The mean (SD) age of the sample was 58.02 (7.821) years. From the total sample, 96.15% (n=375) patients were females while only 3.84% (n=15) of patients were male. Out of the total sample 28 (7.18%) patients had recurrence following breast conservation.

Table 1: Socio-demographic profile of the sample.

		Frequency (N)	Percentage (%)
Age	< 65	274	70.3%
	≥ 65	116	29.7%
Gender	Male	15	3.8%
	Female	375	96.2%
BMI	BMI < 30 kgm^{-3}	352	90.3%
	BMI > 30 kgm^{-3}	38	9.7%
Comorbidities	Diabetes Mellitus	246	63.1%
	Hypertension	184	47.2%
	Bronchial Asthma	149	38.2%

*BMI - Body Mass Index

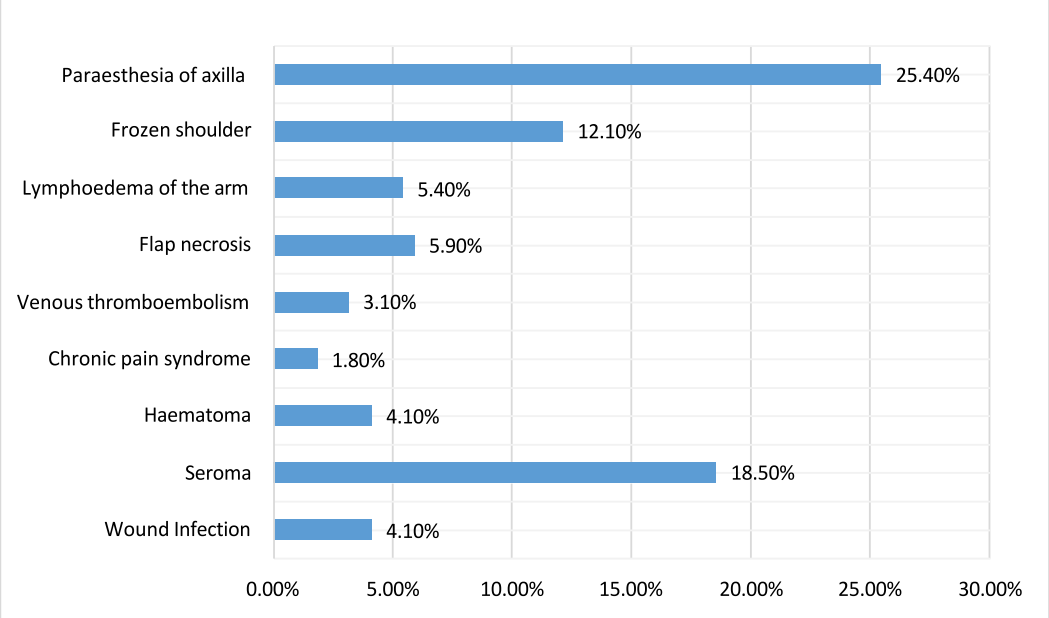

Figure 1: Postoperative complications

Prevalence of postoperative complications

Out of complications studied, paresthesia of the axilla was the most frequently observed complication among study subjects, occurring in 25.4% (n=99) while chronic pain syndrome was the least frequent complication. (n=7; 1.8%). Other complications included seroma formation (18.50%), frozen shoulder (12.10%), flap necrosis (5.90%), lymphoedema of the arm (5.40%), haematoma formation (4.10%), surgical site infection (4.10%) and venous thromboembolism (3.10%) in order of frequency.

Risk factors associated with complications following mastectomy and related axillary procedures

Our analysis focused on the following as the risk factors: age, gender, obesity, diabetes mellitus, hypertension, bronchial asthma, and being a recurrence. Age more than 65 years [OR=6.86 (4.41-9.31)], obesity [OR=25.3 (21.43-33.29)] and being a recurrence [OR=21.2 (10.4-31.8)] were identified as risk factors that were significantly associated with development of wound infection (p<0.05). Same factors were significantly associated with hematoma formation as well [p<0.05, age more than 65 years: OR= 3.43 (0.84-6.02), obesity: OR=5.43 (4.43-6.43), being a recurrence: OR= 7.23 (2.71-11.75)]. Seroma formation was more frequently seen among patients aged more than 65 years [p=0.001, OR=6.6 (5.15-8.04)], patients who were obese (p=0.002, OR=6.8 (4.6-9.0)], patients with diabetes mellitus [p=0.001, OR=4.43 (1.84-7.02)] and patients with a recurrence [p=0.002, OR=2.63 (1.58-3.68)].

Development of flap necrosis and lymphoedema of arm in postoperative patients were seen more commonly among study subjects with age more than 65 years [p<0.05, flap necrosis: OR=15.63 (10.16-21.1), lymphoedema of the arm: OR=4.65 (3.62- 5.68)], with diabetes mellitus [p<0.05, flap necrosis: OR=12.714 (10.844 - 14.584), lymphoedema of the arm: OR=8.5 (7.45-9.55)], with obesity [p<0.05, flap necrosis: OR=13.14 (8.45-17.83), lymphoedema of the arm: OR= 12.15 (5.36-18.94)] and patients having a recurrence episode [p<0.05, flap necrosis: OR=8.23 (3.71-12.75), lymphoedema of the arm: OR=6.41 (5.38-7.44)].

Furthermore, venous thromboembolism was significantly associated with patients aged more than 65 years, those with diabetes mellitus, hypertension, and obesity [p<0.05, age more than 65 years: OR=7.09 (5.07-9.11), diabetes mellitus: OR=6.43 (5.43-7.43), hypertension: OR=7.02 (6.01- 8.03), obesity: OR= 13.14 (8.54-17.74)].

We also noticed a significant association between development of the chronic pain syndrome and that corresponding episode being a recurrence of the disease. [p=0.001, OR=71.33 (59.98-82.68)]. A higher frequency of developing frozen shoulder following mastectomy and related axillary procedures were present among patients of an age more than 65 years [p=0.001, OR= 6.23 (5.04-7.42)], with diabetes mellitus [p=0.002, OR=4.88 (3.64-6.12)] and subjects with a recurrence episode [p=0.011, OR=2.72 (1.32-4.12)].

We identified that an age of more than 65 years as the risk factor which is associated with majority of the complications following mastectomy and related axillary procedures.

Finally, none of the complications were affected by gender or having bronchial asthma as a comorbidity.

Identifying the modifiable risk factors associated with complications following mastectomy and related axillary procedures

Out of the risk factors that showed a significant association, obesity, diabetes mellitus and hypertension were the modifiable risk factors associated with complications following mastectomy and related axillary procedures.

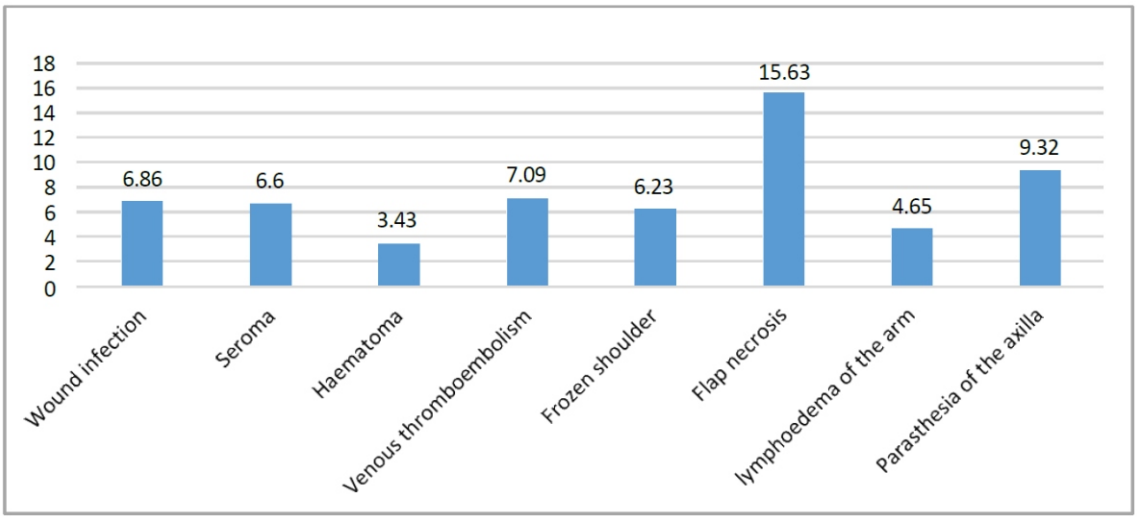

Figure 2: Relative risks of developing complications in patients aged more than 65 years

Discussion

First objective of our study was to determine the incidence of complications following mastectomy and related axillary procedures. Prevalence of postoperative complications vary among studies in the literature. A study done by Gupta *et al.,* revealed that seroma formation as the most common complication (44%) following mastectomy (7). In contrast, in our study, paresthesia of the axilla was the most frequently observed complication among study participants, occurring in 25.4%, while seroma formation being the second most common complication accounting for 18.50%.

In the literature, the rate of hematoma formation following mastectomy is reported to be ranging 0% to 31.2% (8). The rate of haematoma formation observed in our study is 4.10% and it is consistent with above range. In a study done by Maesaka *et al.*, 15 out of 1672 patients had a confirmed diagnosis of venous thromboembolism (0.9%), while our study showed a rate of 3.10% (9).

28% cases of wound infection, 2% cases of flap necrosis and 2% cases of lymphedema were observed in a study done at Yemen (7) Another study showed that the frequencies of surgical site infection and flap necrosis in patients undergoing breast surgery were approximately 8% for each category (4). In contrast, only 4.10% incidence of wound infection was seen in our study while rates of flap necrosis and lymphedema were 5.90% and 5.40% respectively.

A study done by Jayasinghe *et al* in Sri Lanka revealed 27.5% prevalence of chronic pain syndrome (10). Notably, in our study there were only 1.80% cases of chronic pain syndrome.

Although literature mentions that there is no significant association of age as a risk factor for development of complications following mastectomy and related axillary procedures (11, 12), our study showed that being older than 65 years as the risk factor that associated with majority of complications.

In a prospective multicentre study done at France, obesity and diabetes mellitus had significantly increased the incidence of complications following mastectomy (13). This is compatible with our findings, which showed a significant association between obesity and diabetes mellitus with complications. A study done by Yuki Hara *et al.,* have revealed that the body mass index of more than 26 kg/m^{-2} significantly increased the risk of lymphoedema (14). Ten Wolde *et al* have also described that an increased body mass index increased the odds of developing post-operative complications in mastectomy (12). These are consistent with our observations.

Limitations

There are several limitations of our study. The short postoperative period considered in our study generally assess early complications.

Therefore, lymphoedema and chronic pain syndromes may not have been assessed accurately at one months-time. Axillary clearance procedures we considered together as one entity without categorising data according to different procedures. Since different procedures may have different complication profiles with different rates, the true picture may not be revealed. The surgical site infections were also considered as one group in current study without considering its subtypes which may cause a bias in analysis. Further, in our study, seroma formation was assed clinically due to practical constrains of using USS in every patient.

Conclusions and recommendations

This study highlights the significant prevalence of postoperative complications following mastectomy and related axillary procedures, with paresthesia of the axilla being the most common complication observed. Factors such as an age of more than 65 years, obesity, and the presence of chronic conditions like diabetes mellitus, hypertension emerged as critical risk factors associated with many complications, particularly wound infection, seroma formation and venous thromboembolism. Moreover, the present study shows that there is an added risk of developing complications in patients with an recurrence episodes.

These findings underscore the necessity for heightened vigilance in monitoring older patients and those with pre-existing chronic diseases to mitigate the risk of post- operative complications. We recommend to implement comprehensive evaluations of patients, particularly those over 65 years, focusing on factors including obesity and other comorbid conditions to tailor surgical approaches and post-operative care.

Development of educational programs for patients about potential risks associated with mastectomy and related axillary procedures, emphasizing the importance of lifestyle modifications, such as weight management and controlling diabetes mellitus and hypertension is also recommended. It is worth to establish a standardized protocol for early detection and management of post-operative complications, particularly in high-risk groups.

Breast-conservation surgery (BCS) should be considered for eligible patients as it offers comparable oncological safety with reduced postoperative morbidity and better quality of life. Similarly, the adoption of sentinel lymph node biopsy (SLNB) instead of routine axillary lymph node dissection can significantly reduce complications such as lymphedema, paresthesia, and shoulder dysfunction, without compromising disease control.

Authors declare **-** No competing interests.

Ethical approval: Ethical approval for the study was granted by the Ethics Review Committee of the Faculty of Medicine, University of Ruhuna, Sri Lanka.

References

1. Belmonte R, Monleon S, Bofill N, Alvarado ML, Espadaler J, Royo I. Long thoracic nerve injury in breast cancer patients treated with axillary lymph node dissection. *Supportive Care in Cancer.* 2015; **23**0: 169-175.
2. Adesina MA, Olajire TI. Physical and psychological complications of mastectomy: The role of physiotherapy. *World News of Natural Sciences.* 2020; **29**(3): 212-224.
3. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, Bray F. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA: A Cancer Journal for Clinicians.* 2021; **71**(3): 209-249.
4. Goethals A, Rose J. Mastectomy. *In StatPearls* [Internet] 2022 Oct 6. StatPearls Publishing.
5. National Guidelines for the management of Early and Locally Advanced Breast Cancer in Sri Lanka. Sri Lanka: The National Cancer Control Programme - Ministry of Health; June 2021; [20.05.2024].
6. Jagsi R, Jiang J, Momoh AO, Alderman A, Giordano SH, Buchholz TA, Pierce LJ, Kronowitz SJ, Smith BD. Complications after mastectomy and immediate breast reconstruction for breast cancer: a claims-based analysis. *Annals of Surgery.* 2016; **263**(2): 219-227.
7. Gupta R, Sinnett D, Carpenter R, Preece PE, Royle GT. Antibiotic prophylaxis for post-operative wound infection in clean elective breast surgery. *European Journal of Surgical Oncology.* 2000; **26**(4): 363-366.

8. Jonathan M. Bekisz, Carter J. Boyd, David A. Daar, Courtney N. Cripps, Rachel Bluebond-Langner. Haematoma following gender-affirming mastectomy: A systematic review of the evidence. *Journal of Plastic, Reconstructive & Aesthetic Surgery.* 2022; **75**(9): 3108-3121.

9. Maesaka JY, Reis YN, Elias LM, Akerman D, Baracat EC, Filassi JR. Venous thromboembolism incidence in postoperative breast cancer patients. *Clinics (Sao Paulo).* 2023; **78**: 100229.

10. Jayasinghe V, Nandasena S. Prevalence of post mastectomy pain syndrome and its impact on quality of life of breast cancer survival in Sri Lanka. *IJACM.* 2018; **1**(3): 11- 15.

11. Santosa KB, Qi J, Kim HM, Hamill JB, Pusic AL, Wilkins EG. Effect of patient age on outcomes in breast reconstruction: results from a multicenter prospective study. *Journal of the American College of Surgeons.* 2016; **223**(6): 745-754.

12. Ten Wolde B, Kuiper M, de Wilt JH, Strobbe LJ. Postoperative complications after breast cancer surgery are not related to age. *Annals of Surgical Oncology.* 2017; **24**: 1861-1867.

13. Dauplat J, Thivat E, Rouanet P, Delay E, Clough K, Verhaeghe JL, Raoust I, Bannier M, Lemasurier P, Pomel C, STIC-RMI Working Group. Risk factors associated with complications after unilateral immediate breast reconstruction: a French prospective multicenter study. *In Vivo.* 2021; **35**(2): 937-945.

14. Hara Y, Otsubo R, Shinohara S, Morita M, Kuba S, Matsumoto M, Yamanouchi K, Yano H, Eguchi S, Nagayasu T. Lymphedema after axillary lymph node dissection in breast cancer: prevalence and risk factors – a single - center retrospective study. *Lymphatic Research and Biology* 2022; **20**(6): 600-606.