e-ISSN:2602-2079

Volume 9
Issue 5
2025

JOURNAL of Surgery and Medicine

International Medical Journal

JOSAM

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Vol. 9 No. 5 (2025)

Published: 2025-05-31

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J Surg Med. 2025;9(5):57-61.
https://doi.org/10.28982/josam.7833

JOSAM

Research article
https://jsurgmed.com/

Journal of Surgery and Medicine

e-ISSN: 2602-2079

Gender-related differences in survival in locally advanced luminal A breast cancer patients

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Ethics Committee Approval
As this study utilized de-identified data from the SEER database, which is publicly available and maintains patient anonymity, ethical approval and informed consent were not required.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 May 7

Abstract

Background/Aim: Breast cancer is known to exhibit variations in clinical outcomes based on several factors, including molecular subtypes and patient demographics, yet the influence of gender on survival outcomes in patients with locally advanced stage luminal A breast cancer remains underexplored. This study aimed to determine how gender affects the survival of patients with locally advanced stage breast cancer.

Methods: Data were obtained from the Surveillance Epidemiology and End Results (SEER) database. Patients with luminal A molecular subtype and locally advanced stage breast cancer who had been diagnosed between 2010 and 2019 were included in the study. Age, gender, marital status, race, and year of diagnosis were classified as clinical data, and tumor localization, laterality, grade, stage, surgical status, radiotherapy and chemotherapy status, cause of death, and survival time were classified as oncological data. Data were compared based on gender.

Results: The study included a total of 46,730 patients. A very small percentage of the patients were male (1.2%), while 98.8% were female. Male patients were significantly older and had a higher marriage rate. Racial distribution differed slightly with more black patients among the males. Grade 2 tumors were most prevalent in both genders, but males had higher grade 3 tumors. Stage 3B and 3C tumors were more common in males, but no significant difference for Stage 3C based on gender was detected. Surgical rates were similar between genders, while females had higher rates of treatment with radiotherapy and chemotherapy. Females exhibited significantly higher overall survival rates (64.4% versus 52.2%). Cancer-specific survival did not differ significantly (76.3% versus 72.1%). Males had a 1.6 times higher overall mortality risk, which was reduced to 1.3 times after adjusting for other prognostic factors.

Conclusion: No difference in cancer-specific survival between men and women with locally progressed luminal A breast cancer was found. These results highlight the significance of considering gender-specific characteristics while managing patients and predicting their prognosis. To fully understand the underlying mechanisms behind the survival differences between male and female patients, further studies are required.

Keywords: breast cancer, luminal A, hormone positive, survival

Introduction

One of the most common cancers in the world and the leading cause of cancer-related deaths in women is breast cancer. Breast cancer prognosis and treatment outcomes might vary depending on several variables, such as molecular subtypes and patient characteristics. A molecular subtype of breast cancer, luminal A, has a better prognosis than other subtypes and is characterized by the presence of hormone receptors. Nevertheless, it is crucial to investigate potential variations in survival outcomes within this subtype, especially when considering gender-related differences [1,2].

Gender-related characteristics may have an impact on how breast cancer patients respond to treatment and how their clinical course develops as described in previous research studies. According to several studies, male and female breast cancer patients have different survival rates; females usually have better outcomes [3,4]. The effect of gender, specifically in individuals with locally advanced luminal A breast cancer, on survival outcomes is still unknown. To determine whether a gender-related survival difference in patients with locally advanced luminal A breast cancer exists, this study investigated this possible gender-related difference.

Materials and methods

Study population

In this retrospective study, data were obtained from the Surveillance Epidemiology and End Results (SEER) database, specifically the SEER Research Plus 17 Registries. Locally advanced breast cancer patients diagnosed with a molecular subtype classified as luminal A between 2010 and 2019 were included in the study. Patients with stage 2B, 3A, 3B, or 3C breast cancer were considered eligible for the analysis.

Data collection and variables

Clinical data, including age, gender, marital status, race, year of diagnosis, tumor localization (central localization, upper outer quadrant, upper inner quadrant, lower outer quadrant, lower inner quadrant, overlapping), laterality (right/left), grade, stage, surgical status, radiotherapy and chemotherapy status, cause of death, and survival time were collected from the SEER database. Patients with early-stage or metastatic disease or missing data were excluded from the study to ensure the homogeneity of the locally advanced luminal A breast cancer cohort.

Efforts to address potential sources of bias

In this study, several steps were taken to minimize potential sources of bias and ensure the validity of the findings. First, data were obtained from the SEER database, which includes a comprehensive and standardized collection of patient information thus reducing selection bias. We included patients diagnosed with luminal A breast cancer between 2010 and 2019 to ensure a consistent timeframe and limit variations in treatment protocols over time. Patients with early stage, metastatic disease, and/or missing data were excluded to maintain the homogeneity of the study cohort. To control for confounding variables, we performed multivariate analyses adjusting for demographic factors (age, gender, marital status, race), clinical characteristics (tumor grade and stage), and treatment modalities (surgery, radiotherapy, and/or chemotherapy). By adjusting for these variables, we aimed to isolate the effect of gender on survival outcomes. Additionally, we used established statistical methods, such as the Cox regression analysis, to assess the impact of these variables on overall and cancer-specific survival. Despite these efforts, we acknowledge that inherent limitations of retrospective studies, such as unmeasured confounding factors and reliance on the accuracy of recorded data, still may have introduced some bias.

Statistical analysis

Statistical analyses were performed using SPSS for Windows (version 22.0, SPSS Inc., Chicago, IL, USA). The Kolmogorov–Smirnov test and box plot graphs were used to assess the study data's conformity to the normal distribution of the variables together with descriptive statistical methods (mean, standard deviation). An independent t-test was used to compare groups of normally distributed variables. To compare qualitative data, the Pearson's chi-squared test was applied. Overall survival (OS) was calculated based on who was still alive at the end of the study or at the last follow-up. Breast cancer-specific survival was calculated for individuals who were alive at the end of the study period, died due to another cause, or were still living at their last follow-up and whose cause of death was breast cancer. Kaplan–Meier analysis and the log-rank test were used to assess the results of survival analyses. Cox regression analysis was used for univariate and multivariate analyses. Results were considered significant at the *P*-value <0.05 level.

Results

The study included 46,730 patients in total. The percentage of male patients was 1.2% (n=578), while 98.8% were female (n=46,152). The mean age of males was significantly higher (male: 64.9 [12.17] years; Female: 58.5 [14.21] years; $P<0.001$). The rate of being married was significantly higher in males compared to females (Male=65.2%; Female=55.9%; $P<0.001$).

Grade 2 tumors were most common in both groups with grade 1 tumors accounting for 12.3% in females and 7.3% in males, grade 2 tumors accounting for 50.8% in females and 46.7% in males, and grade 3 tumors accounting for 36.9% in females and 46% in males. Both groups had the largest percentage of Stage 2B cancers with 52% of females and 45.8% of males having these tumors. Females were more likely to be in Stage 3A than men. 29.2% of females and 23.7% of males were in stage 3B. Males had a larger percentage of Stages 3B and 3C cancer. Stage 3C was found in 9.8% in females and 11.42% in males, while Stage 3B affected females at a rate of 9.1% and males at a rate of 19%. Regarding the proportions of Stage 3C based on gender, no significant difference was found (Table 1).

No significant difference in the surgical rate between males and females (95.3% versus 94.8%; $P=0.547$) was found. Radiotherapy was used more frequently for women (59% versus 49.5%; $P=0.001$) than in men. Chemotherapy was used for 69.5% of female patients compared to 62.1% of male patients ($P<0.001$) as shown in Table 1. The median survival time was 54.06 (31.77) months and ranged from 0 to 119 months.

Females had a considerably greater overall survival rate ($P<0.001$). Females had a 5-year survival rate of 80.7%, while males had a rate of 71.2%. Males had an overall survival rate of

52.2% and females of 64.4% (Figure 1). No significant difference in terms of cancer-specific survival was found. Most females (86.9%) and 83.3% of males had cancer-specific survival at five years, whereas 76.3% of females and 72.1% of males had cancer-specific survival overall (P=0.221) as shown in Figure 2.

Table 1: Clinical, pathological and oncological results of the patients

		Female n (%)	Male n (%)	P-value
Age, mean (SD)		58.5 (14.21)	64.9 (12.17)	<0.001[a]
Marital status	Married	25787 (55.9)	377 (65.2)	<0.001[b]
	Others	20365 (44.1)	201 (34.8)	
Race	White	35778 (77.5)	443 (76.6)	<0.001[b]
	Black	5336 (11.6)	94 (16.3)	
	Others	5038 (10.9)	41 (7.1)	
Tumor localization	Upper outer quadrant	15924 (34.5)	54 (9.3)	<0.001[b]
	Upper inner quadrant	3954 (8.6)	17 (2.9)	
	Lower outer quadrant	3345(7.2)	24 (4.2)	
	Lower inner quadrant	1805 (3.9)	7 (1.2)	
	Central	3340 (7.2)	318 (55)	
	Overlapping	10598 (23)	80 (13.8)	
	Unknown	7186 (15.6)	78 (13.5)	
Laterality	Right	22944 (49.7)	271 (46.9)	0.568[b]
	Left	23194 (50.3)	307 (53.1)	
	Bilateral	8 (<0.1)	0	
	Unknown	6 (<0.1)	0	
Grade	1	5682 (12.3)	42 (7.3)	<0.001[b]
	2	23432 (50.8)	270 (46.7)	
	3	17038 (36.9)	266 (46)	
Stage	2B	24009 (52)	265 (45.8)	<0.001[b]
	3A	13455 (29.2)	137 (23.7)	
	3B	4178 (9.1)	110 (19)	
	3C	4510 (9.8)	66 (11.4)	
Surgery	Performed	43737 (94.8)	551 (95.3)	0.547[b]
	Not performed	2415 (5.2)	27 (4.7)	
Radiotherapy	Yes	27252 (59)	286 (49.5)	<0.001[b]
	No	18900 (41)	292 (50.5)	
Chemotherapy	Yes	32089 (69.5)	359 (62.1)	<0.001[b]
	No	14063 (30.5)	219(37.9)	
Vital Status	Alive	37373 (81)	414 (71.6)	<0.001[b]
	Breast	5660 (12.3)	76 (13.1)	
	Other reason	3119 (6.8)	88 (15.2)	
Survival time, mean (SD) (min -max)		54.06 (31.77) (0-119) month		

a: Independent samples t-test, b: Pearson Chi-Square Test, SD: standard deviation

Figure 1: Overall survival graphic

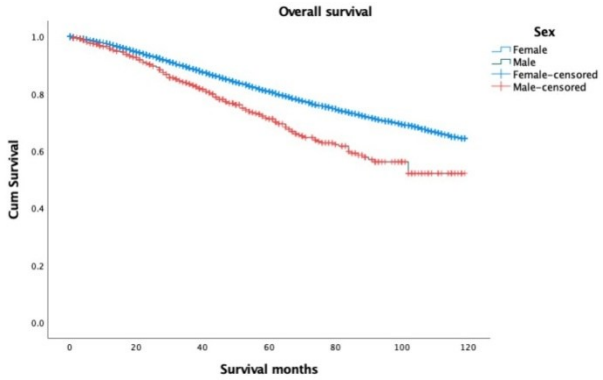
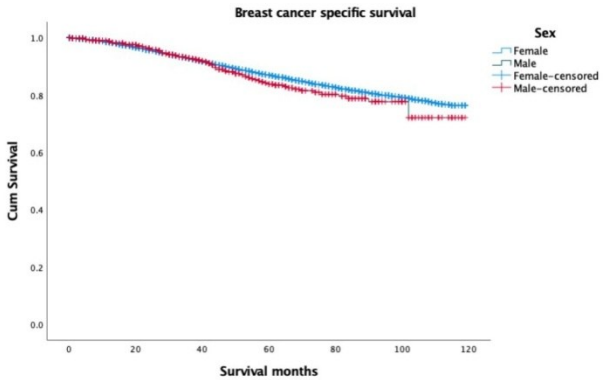


Figure 2: Cancer specific survival graphic



Males had a 1.6-fold higher overall death risk than females (P<0.001, hazard ratio [HR]: 1.604; 95% confidence interval [CI]: 1.375–1.872]). The risk of death was 1.3 times higher in males than in females after the multivariate analysis adjusted for marital status, race, grade, stage, and surgery, chemotherapy, and/or radiotherapy status (P<0.001, HR: 1.315; 95% CI: 1.126–1.535). No significant difference for cancer-specific death risk (P=0.221) as shown in Table 2. Tables 3–6 provide specific outcomes regarding prognostic factors for OS and cancer-specific survival for both males and females.

Discussion

The purpose of this study was to determine if gender-related differences in survival among patients with locally advanced stage luminal A breast cancer exist. We observed that several important distinctions between the clinical features and survival rates of males and females in this patient population were present.

Males with locally advanced luminal A breast cancer were found to be substantially older than females according to the examination of patient demographics. This age difference may have been caused by a delay in diagnosis or by gender-specific changes in tumor biology [5,6]. Male patients additionally showed a larger proportion of these patients were married, indicating possible social and support system components that could have affected survival results [7,8].

Males and females showed different tumor features, including tumor location, grade, and stage. The most frequent tumor localization varied between genders with a more prevalent upper outer quadrant in females versus a central localization in males. This variation could have been caused by differences in tumor biology or anatomical elements [6,9].

Males were more likely than females to have higher-grade tumors (grade 3), which are typically linked to worse prognoses. Similarly, the more advanced stages (3B and 3C) were more prevalent in men, indicating a more aggressive disease in this cohort. The differences in survival between genders may have been caused by these variations in tumor features [7,10].

Regarding treatment options, no significant differences in the rates of surgical treatment between males and females were found, indicating equal access to and use of surgical treatments. In contrast to males, females received radiotherapy and chemotherapy at higher rates. Depending on the features of the tumor and the response rates, several treatment techniques may be advised. Females were more likely to receive radiotherapy and chemotherapy than males, which may explain why they have better survival rates [5,11–13].

These results are supported by previous research reporting better outcomes in female breast cancer patients [3,5,7]. However, no significant difference in cancer-specific survival between genders was detected, suggesting that factors other than cancer progression may influence the observed survival differences. The survival analysis demonstrated that females presented significantly higher overall survival rates compared to males and that a significant difference in the 5-year survival rates was present.

Males had a considerably higher overall risk of mortality than females according to the multivariate analysis that adjusted for several confounding variables. Males still presented a greater risk of death after adjusting for marital status, race, grade, stage, surgery, chemotherapy, and radiotherapy. This finding indicates

Table 2: Cox regression analysis based on gender

	Overall survival				Cancer-specific survival			
	Univariate				Univariate			
			95% CI for HR				95% CI for HR	
	P-value	HR	Lower	Upper	*P*-value	HR	Lower	Upper
Female	Reference				Reference			
Male	<0.001	1.604	1.375	1.872	0.221	1.152	0.918	1.444
	Multivariate							
			95% CI for HR					
	P-value	HR	Lower	Upper				
Female	Reference							
Male	<0.001	1.315	1.126	1.535				

CI: confidence interval, HR: hazard ratio

Table 3: Cox regression analysis of female patients overall survival

		Univariate				Multivariate			
		P-value	HR	95% CI for HR		*P*-value		95% CI for HR	
				Lower	Upper		HR	Lower	Upper
Marital status	Married		Reference				Reference		
	Others	<0.001	1.919	1.840	2.003	<0.001	1.587	1.506	1.672
Surgery	Yes		Reference				Reference		
	No	<0.001	4.860	4.565	5.174	<0.001	4.733	4.375	5.120
Radiotherapy	Yes		Reference						
	No	<0.001	1.909	1.830	1.991	<0.001	1.579	1.498	1.663
Chemotherapy	Yes		Reference						
	No	<0.001	2.248	2.156	2.345	<0.001	1.398	1.324	1.477
Grade	I		Reference				Reference		
	II	<0.001	1.259	1.167	1.358	<0.001	1.616	1.447	1.805
	II	<0.001	2.033	1.884	2.193	<0.001	3.371	3.023	3.759
Stage	2B		Reference				Reference		
	3A	<0.001	1.301	1.236	1.370	<0.001	1.638	1.535	1.748
	3B	<0.001	3.367	3.158	3.589	<0.001	3.857	3.553	4.187
	3C	<0.001	2.481	2.336	2.635	<0.001	3.506	3.226	3.768

Table 4: Cox regression analysis of female patients cancer-specific survival

		Univariate				Multivariate			
		P-value	HR	95% CI for HR		*P*-value		95% CI for HR	
				Lower	Upper		HR	Lower	Upper
Marital status	Married		Reference				Reference		
	Others	<0.001	1.565	1.499	1.634	<0.001	1.353	1.283	1.427
Surgery	Yes		Reference				Reference		
	No	<0.001	2.632	2.455	2.821	<0.001	3.054	2.796	3.335
Radiotherapy	Yes		Reference						
	No	<0.001	1.381	1.318	1.447	<0.001	0.880	0.854	0.906
Chemotherapy	Yes		Reference						
	No	<0.001	2.182	2.083	2.285	<0.001	1.486	1.399	1.579
Grade	I		Reference				Reference		
	II	<0.001	1.332	1.235	1.437	<0.001	1.630	1.459	1.821
	II	<0.001	2.210	2.047	2.386	<0.001	3.324	2.979	3.710
Stage	2B		Reference				Reference		
	3A	<0.001	1.581	1.500	1.666	<0.001	1.828	1.712	1.953
	3B	<0.001	2.590	2.422	2.769	<0.001	2.884	2.648	3.141
	3C	<0.001	2.970	2.794	3.157	<0.001	3.754	3.490	4.040

Table 5: Cox regression analysis of male patients overall survival

		Univariate				Multivariate			
		P-value	HR	95% CI for HR		*P*-value		95% CI for HR	
				Lower	Upper		HR	Lower	Upper
Marital status	Married		Reference				Reference		
	Others	0.002	1.632	1.198	2.223	0.017	1.446	1.070	2.008
Surgery	Yes		Reference				Reference		
	No	<0.001	5.186	3.165	8.497	<0.001	3.924	2.333	6.598
Radiotherapy	Yes		Reference						
	No	<0.001	1.684	1.231	2.303	0.319	1.188	0.847	1.667
Chemotherapy	Yes		Reference						
	No	<0.001	2.269	1.668	3.086	<0.001	2.062	1.493	2.847
Grade	I		Reference						
	II	0.372	1.370	0.686	2.735				
	II	0.132	1.699	0.852	3.387				
Stage	2B		Reference						
	3A	0.792	1.053	0.715	1.552				
	3B	0.123	1.389	0.915	2.110				
	3C	0.652	1.119	0.687	1.821				

Table 6: Cox regression analysis of male patients cancer-specific survival

		Univariate				Multivariate			
		P-value	HR	95% CI for HR		*P*-value		95% CI for HR	
				Lower	Upper		HR	Lower	Upper
Marital status	Married		Reference				Reference		
	Others	<0.001	2.417	1.540	3.793	<0.001	2.161	1.365	3.423
Surgery	Yes		Reference				Reference		
	No	<0.001	6.850	3.497	13.417	<0.001	5.169	2.617	10.212
Radiotherapy	Yes		Reference						
	No	0.450	0.917	0.732	1.148				
Chemotherapy	Yes		Reference						
	No	0.451	0.826	0.499	1.368				
Grade	I		Reference				Reference		
	II	0.132	4.627	0.630	33.974	0.117	4.931	0.670	36.285
	II	0.031	8.819	1.216	63.973	0.032	8.799	1.211	63.919
Stage	2B		Reference						
	3A	0.039	0.687	0.482	0.981				
	3B	0.799	0.951	0.644	1.403				
	3C	0.799	0.941	0.592	1.497				

that gender alone, independent of other demographic and treatment-related characteristics, may contribute to survival differences [6,14–16].

The causes of the gender-related survival difference in patients with locally advanced stage luminal A breast cancer are still unknown. These differences may be influenced by hormonal factors, variations in tumor biology, treatment outcomes, and social support systems [4,11,17]. To fully understand the specific factors and mechanisms at play, further investigations are required.

Limitations

It is critical to recognize some of the limitations of this study. First, the study design introduces inherent biases and restrictions related to secondary data analysis due to its retrospective character and reliance on data from the SEER database. Second, the database does not contain information concerning some characteristics that might have an impact on survival outcomes, such as comorbidities and treatment compliance. Additionally, most participants in the study were female, which restricted the applicability of the results to males with luminal A breast cancer.

Conclusion

In conclusion, this study showed that patients with locally advanced stage luminal A breast cancer had different survival rates according to their gender. Even after adjusting for various confounding factors, females still had higher overall survival rates than males. These findings highlight the significance of considering gender-specific characteristics while managing and predicting the prognosis of patients with luminal A breast cancer. To improve outcomes for male breast cancer patients, future research should concentrate on elucidating the underlying mechanisms causing the survival differences between male and female patients and designing targeted therapies for both groups.

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J Surg Med. 2025;9(5):62-66.
https://doi.org/10.28982/josam.8034

JOSAM

Research article
https://jsurgmed.com/

Journal of Surgery and Medicine

e-ISSN: 2602-2079

The effect of wirelessly-enabled antepartum maternal-fetal monitoring on patient comfort, labor, and obstetric-neonatal outcomes: A prospective cohort study

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Ethics Committee Approval
The study was approved by ethics committee of Amasya University (Date: July 8, 2021, Number: 122).
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 May 13

Abstract

Background/Aim: More than half of perinatal deaths result from stillbirth, with one-third transpiring during the intrapartum period. Therefore, antepartum maternal-fetal monitoring is crucial. This study aims to evaluate the impact of wireless-enabled antepartum maternal-fetal monitoring during labor on enhancing patient comfort, labor duration, and obstetric-neonatal outcomes.

Methods: This study employed a prospective cohort methodology. From August 1st, 2021 to August 12th, 2023, 95 pregnant women who initiated active labor were followed using wireless-enabled antepartum maternal-fetal monitoring, and 95 women who used standard cardiotocography during labor. The study included pregnant women who were at least 37 weeks pregnant, had a dilation of 3–4 cm and 50% effacement, no ruptured membrane, and no risky pregnancy conditions (e.g., preeclampsia and HELLP syndrome), and did not use induction methods (e.g., oxytocin). Women who exhibited dilation and effacement beyond these parameters were not included in the study, but those with less were included when they reached these criteria. We compared demographic characteristics, labor duration, movement limitations due to cardiotocography, feelings of discomfort from the probe (assessed using a visual analog scale), and obstetric-neonatal outcomes between the two groups.

Results: The groups were homogeneous in terms of demographic characteristics ($P>0.05$). The average systolic blood pressure, measured every 2 h during childbirth, was higher in the control group ($P<0.001$). The visual analog scale value associated with continuous wear of the cardiotocography probe and movement restrictions was higher in the control group ($P<0.001$). Despite a significant difference in birth weeks between the groups ($P=0.043$), there was no significant difference in birth weights ($P=0.373$). The duration of labor was shorter in the study group ($P=0.011$). There was no significant difference in obstetric and neonatal outcomes ($P>0.05$).

Conclusion: Wirelessly-enabled antepartum maternal-fetal monitoring provides greater patient comfort and has a positive impact on labor duration.

Keywords: wirelessly-enabled antepartum maternal-fetal monitoring, patient comfort, labor duration, obstetric and neonatal outcomes

How to cite: Taşkömür AT. The effect of wirelessly-enabled antepartum maternal-fetal monitoring on patient comfort, labor, and obstetric-neonatal outcomes: A prospective cohort study. J Surg Med. 2025;9(5):62-66.

Introduction

More than 6.3 million perinatal deaths occur annually worldwide. Over 60% of these entail deaths in the womb, with a third of them resulting from asphyxia in the intrapartum period [1]. The prevalence of such incidents is particularly higher in developing countries [2]. Because of this, antenatal surveillance is fundamentally important. Newly developed maternal-fetal monitoring devices, enhanced by wireless technology, have been introduced to help with antenatal monitoring, particularly in remote areas. In areas where maternal-fetal monitoring proves difficult, such devices usher ease for patients and ensure constant fetal monitoring.

Cardiotocography devices enable external monitoring of the fetus during non-stress testing, contraction stress testing, and labor. Studies have demonstrated that devices leveraging wireless, remote prototype technology can be effectively employed in external fetal monitoring [3]. The reliance on standard cardiotocographs to be used and interpreted by a specialized healthcare team can create strain during prenatal follow-up. Utilizing wireless devices personally also mitigates this pressure. This offers considerable benefits for patients with gestational hypertensive illnesses and gestational diabetes, or those with high-risk pregnancies. Its ease of use is also advantageous [4,5]. Some believe it could even decrease maternal and fetal morbidity and mortality associated with pregnancy complications [6].

During active labor, the fetus needs to be connected to cardiotocographs for regular monitoring. In high-risk pregnancies, this monitoring becomes continuous, necessitating the patient to remain bedridden. The constant requirement to lie down and limited mobility can make an already challenging labor process even more difficult. Wireless devices remove this restriction on patients' movements, allowing them the freedom to move as they wish, and studies have shown this to increase patient compliance [3].

Although the impact on fetal-maternal outcomes is generally considered positive, there are limited studies on this topic. Similarly, minimal research has been conducted to evaluate its effect on labor duration. This study was designed to assess patient discomfort related to the use of fetal monitors and restricted movement during labor, as well as to gauge the devices' influence on the length of labor and their implications for obstetric-neonatal outcomes.

This study was designed to assess the emotional discomfort associated with the attachment of cardiotocography probes and the resulting immobility in patients during labor. It also aimed to analyze the effects of these devices on labor duration and obstetric-neonatal outcomes.

Materials and methods

The study received approval from the ethics committee of Amasya University (Date: July 8, 2021, Number: 122) and was conducted following the principles of the Helsinki Declaration.

This study is a prospective cohort study. We included nulliparous and multiparous pregnant women aged between 19 and 40 years, whose active labor commenced between August 1st, 2021, and August 12th, 2023, and was beyond 37 weeks. The study aimed to evaluate the effect on labor duration, hence, it included pregnant women with 3–4 cm dilation and 50% or more effacement, irrespective of the status of the amniotic membrane.

Patients less dilated (less than 3–4 cm) or less effaced (less than 50%), who reached this stage without membrane rupture, were also included. However, those with ruptured membranes were excluded from the study. Individuals whose initial evaluation surpassed this cervical dilation and effacement were not considered for the study.

Additionally, we did not include patients who underwent labor induction procedures (e.g., with oxytocin and prostaglandin E2). Only patients with spontaneous labor progression were incorporated into the study.

To avoid impact on obstetric and neonatal outcomes, patients aged under 19 years or over 40 years, those diagnosed with hypertensive disease of pregnancy, diabetes history, preterm labor, intrauterine growth retardation, fetal anomalies, severe hyperemesis gravidarum, thrombophilia, impending abortion, hepatic, renal or autoimmune diseases, and those with a contraindication for normal vaginal birth (e.g., breech situs, large fetus) were excluded from the study. Pregnant women fulfilling these criteria were informed about the study and provided their consent. They were assigned to two groups based on their order of arrival. The first 95 patients made up the study group and were monitored with wirelessly-enabled antepartum maternal-fetal technology throughout labor. The following 95 patients were followed using standard cardiotocography. The patient's blood pressure was checked every 2 h, and vaginal examinations were also performed bi-hourly. Cardiotocography follow-up was maintained throughout labor. Routine hemogram, biochemistry, and full urinalysis were requested for patients. Pregnant women exhibiting abnormal values such as hemolysis, elevated liver enzymes, low platelets (indicative of HELLP syndrome), and preeclampsia were excluded from the study.

In the study, a Luckcome DS 2013 device was employed for standard cardiotocography, and a HwatimeT10 maternal/fetal integrated wireless monitor device (Product Code: 67402-K3493) was utilized.

The demographic characteristics of both groups (age, height, weight, body mass index [BMI], parity, obstetric history, known diseases, previous surgeries) were recorded. The initial vaginal examination, as well as subsequent examinations conducted every 2 h, were noted. Blood pressure measurements were also taken every 2 h. Other recorded data included the timing of the first vaginal examination, the time of birth, the week of gestation, the type of birth, the baby's weight, indications for a cesarean section, 1st and 5th Apgar scores of the baby, and whether the baby required intensive care. Half an hour after birth, the discomfort experienced by the patient due to the attachment of the cardiotocography probe and mobility restrictions related to the device was evaluated using the visual analog scale (VAS). The VAS is a scale that extends 10 cm, with values ranging from 0 to 10; with zero representing no pain and 10 indicating extreme pain [7].

Power analysis

G*Power version 3.1.9.7 was used to determine the sample size for this study. Calculations factored in Cohen's 1988 recommendation for medium or small effect size (medium effect d=0.5; small effect d=0.2) [8]. Accordingly, it was derived that the two independent groups' difference analysis necessitates a reach of 190 persons to maintain a medium effect size, 80% confidence interval, and 5% margin of error (study group 95, control group 95) [9]. A posthoc power analysis conducted after the study confirmed that the calculated power was achieved with the sample size of 190 individuals (1-β=0.80; Critical t=1.97, Df=188).

Statistical analysis

All statistical analyses were conducted using the SPSS software package (v. 23.0). We evaluated compliance with the normal distribution using Levene's test. For intergroup comparisons, we employed the Mann-Whitney U test and the independent sample t-test for variables that were non-normally and normally distributed, respectively. The Chi-square test was used to analyze the relationships between categorical variables. It was predetermined that $P<0.05$ would be considered statistically significant.

Results

The study group consisted of pregnant women monitored using wirelessly-enabled antepartum maternal-fetal monitoring (n=95), while those who were followed using standard cardiotocography made up the control group (n=95). There was no significant difference between the two groups in terms of demographic characteristics such as age, height, weight, BMI, parity, obstetric history, known disease, and previous surgery ($P>0.05$) (Table 1).

Table 1: Comparison of demographic characteristics of the groups.

		Study group n=95	Control group n:95	P-value
		Mean (SD)	Mean (SD)	
Age (year)		27.49 (4.94)	27.69 (4.88)	0.634
Weight (kg)		76.86 (11.08)	74.64 (10.54)	0.159
Height (cm)		162.16 (4.97)	162.37 (5.45)	0.761
BMI (kg/m2)		29.19 (3.78)	28.31 (3.79)	0.118
		n (%)	n (%)	
Parity	Nulliparity	34 (35.8%)	33 (43.7%)	0.879
	Multiparity	61 (64.2%)	62 (65.3%)	
Education	Primary school	9 (9.5%)	13 (13.7%)	0.288
	Middle school	14 (14.7%)	8 (8.4%)	
	High school	42 (44.2%)	36 (37.9%)	
	University	30 (31.6%)	38 (40.0%)	
Previous surgery	Yes	6 (6.3%)	8 (8.4%)	0.579
	No	89 (93.7%)	87 (91.6%)	
Chronic disease	Yes	2 (2.1%)	4 (4.2%)	0.407
	No	93 (97.9%)	91 (95.8%)	

P-values were calculated with the independent t-test (maternal weight), Mann-Whitney U test, and Chi-Square Test (Parity, education, previous surgery, chronic disease).

The average blood pressure, measured every 2 h, was taken. The systolic blood pressure was higher in the control group ($P<0.001$).

There was no difference in terms of cervical dilatation and effacement in the vaginal examinations of the patients ($P=1.000$ and $P=0.134$; respectively) (Table 2).

The duration of labor was shorter in the study group compared to the control group ($P=0.011$) (Table 2).

The discomfort VAS values from the cardiotocography probe and the movement limitation for the patient were higher in the control group ($P<0.001$ and $P<0.001$, respectively) (Table 2).

Table 2: Comparison of the groups' average blood pressures, blood sugars, cervical examinations during hospitalization, duration of labor, and feeling uncomfortable with the NST probe inserted during labor and restriction of movement during labor.

	Study group n: 95	Control group n: 95	P-value
	Mean (SD)	Mean (SD)	
Systolic blood pressure (mm/Hg)	101.79 (10.91)	110.63 (8.96)	<0.001
Diastolic blood pressure (mm/Hg)	70.11 (7.64)	72.11 (8.86)	0.069
Cervical dilatation during hospitalization (cm)	4.00 (0.77)	4.00 (0. 72)	1.00
Cervical effacement during hospitalization (%)	61.47 (11.57)	58.95 (10.56)	0.134
Duration of labor (hour)	8.27 (1.86)	8.95 (1.90)	0.011
Feeling uncomfortable with the NST probe inserted during labor	2.61 (1.05)	9.14 (1.19)	<0.001
Restriction of movement during labor	3.14 (1.19)	9.18 (1.18)	<0.001
Serum glucose (mg/dl)	92.69 (18.74)	93.57 (15.56)	0.743

P-values were calculated with the independent t-test (maternal and infant weight), Mann-Whitney U test, and Chi-Square Test (Parity, education, previous surgery, chronic disease, delivery type, indications of cesarean, neonatal intensive care needs)

In comparing the obstetric and neonatal results of both groups, only the birth week was lower in the study group ($P=0.043$). No significant differences were observed in other results such as delivery type, indications of cesarean, infant weight, 1st-minute Apgar scores, 5th-minute Apgar scores, and neonatal intensive care needs ($P>0.05$) (Table 3).

Table 3: The results of obstetric and neonatal outcomes.

		Study group n: 95	Control group n: 95	P-value
		n (%)	n (%)	
Delivery type	Vaginal birth	84 (88.4%)	85 (89.5%)	0.817
	Cesarean	11 (11.6%)	10 (10.5%)	
Indications of cesarean	Vaginal birth	84 (88.4%)	85 (89.5%)	
	Fetal distress	6 (6.3%)	6 (6.3%)	
	Cephalopelvic disproportion	5 (5.3%)	3 (3.1%)	
	Prolonged action	0 (0.0%)	1 (1.1%)	
Neonatal intensive care needs	Yes	8 (8.4%)	15 (15.8%)	0.120
	No	87 (91.6%)	80 (84.2%)	
		Mean (SD)	Mean (SD)	
Birth week (week)		38.94 (1.36)	39.24 (1.55)	0.043
Infant weight (gram)		3254.26 (342.15)	3307.68 (471.65)	0.373
1st minute Apgar scores		8.62 (0.93)	8.54 (0.98)	0.322
5th minute Apgar scores		9.47 (0.72)	9.37 (0.81)	0.410

P-values were calculated with the independent t-test (infant weight), Mann-Whitney U test, and Chi-Square Test (Delivery type, indications of cesarean, neonatal intensive care needs)

Discussion

Giving birth is a challenging process for women. This period often restricts the women's free movement, as they are typically bedridden and tethered to standard cardiotocography devices used for fetal heartbeat monitoring. Such restrictions can make the process even more daunting and uncomfortable. Thus, it is crucial to employ new technological devices that can make the birth process easier. Research indicates that wireless cardiotocography devices, which eliminate the movement restriction experienced by expectant mothers due to the probes attached to their abdomens during labor, enhance patient compliance [3]. These devices are also expected to decrease maternal and fetal morbidity and mortality from pregnancy complications [6]. However, assessing the impact of these novel devices in this context is currently in the research stage. Among the potential benefits of these devices is their possible influence on labor duration and obstetric and neonatal outcomes, as a result of improved patient compliance and the mobility they offer throughout the childbirth process. In light of this, the current study compares labor duration and obstetric and neonatal

outcomes of patients who used these devices against those who were subjected to standard cardiotocography, the routine practice.

The aim of wireless antepartum fetal monitoring is to track pregnant women in rural places where access to gynecologists and obstetricians may be challenging. It is particularly effective in remote and economically disadvantaged areas for identifying high-risk pregnancies. Furthermore, this method enables the appropriate antenatal follow-up of these women in suitable medical facilities.

In this respect, the plan aimed to achieve more favorable results with high-risk pregnancies, enhance the standard of health services, and decrease their costs. Evaluations from studies conducted have confirmed the successful usage of wireless antepartum fetal monitors. However, it was observed that these monitors have no impact on obstetric and neonatal outcomes [3,10]. In a research carried out by Mhajna et al. [11], several different wireless devices were utilized to assess both fetal and maternal heart rates, showing results comparable to pre-existing standard methods. Nevertheless, neither obstetric nor neonatal outcomes were evaluated.

Similarly, the study conducted by Mugyenyi et al. [6] found that wireless devices functioned comparably to standard methods, proving comfortable for use by both pregnant women and physicians. They emphasized the need for additional studies to evaluate these devices' effects on perinatal outcomes and costs.

To understand this, we assessed the discomfort caused by the device's probe and the discomfort resulting from movement restriction using a VAS. In both scenarios, the VAS values were consistently higher with the standard device. From this, we can infer that patient compliance and comfort were superior with the wireless antepartum fetal monitor. In the study, pregnant women's blood pressure in both groups was measured on a bi-hourly basis. The mean systolic blood pressure was significantly lower in those monitored with a wireless antepartum fetal monitor. This leads us to question if a higher VAS score, that is, less comfort, might affect blood pressure. Further studies are required for a better evaluation of these findings.

The study evaluated obstetric (delivery type, indications for cesarean, week of birth, and infant weight) and neonatal outcomes (1st and 5th minute Apgar scores, and neonatal intensive care needs). The birth week was significantly higher in the control group, but there was no significant difference seen between the groups in terms of the other outcomes.

The study also evaluated the duration of labor effects from each device. Pregnant women monitored with a wireless antepartum fetal monitor had significantly shorter labor compared to those using standard devices. Even though the groups showed similar cervical effacement/dilatation during hospitalization, and the birth weeks were significantly higher in the control group, the parity and infant weights remained similar. This implies that the effect of shorter labor duration in the study group on its significance was minimal. In other words, it suggests that other factors potentially affecting birth duration were equal between the groups.

Limitations and strengths

The study does have certain limitations that need consideration. The scope of the study could have been expanded if patients were monitored with these devices throughout the pregnancy as well as during labor, offering a more comprehensive evaluation of obstetric and neonatal outcomes. The power of the study could also have been enhanced with a larger number of subjects. Still, the study's strength lies in that it assesses obstetric and neonatal outcomes along with labor duration, a topic on which there is little research available. Variables that could influence the study's results, including patient parity and infant weight, require consideration, especially for determining birth duration. Fortunately, these parameters did not differ between the study groups. To best assess patient mobility limitations due to cardiotocography and the discomfort of being attached to the probe, evaluations were conducted after a half-hour rest period post-birth, utilizing the VAS.

Conclusions

The study indicates that patients monitored with wirelessly-enabled antepartum maternal-fetal monitoring during childbirth experienced enhanced comfort. Other findings showed lower systolic blood pressure and shorter delivery time with the use of this wireless monitoring. These results may be attributed to the comfort provided by the device. Specifically, the diminished pain duration, afforded by these devices, can be viewed as an additional benefit and source of comfort for women enduring childbirth. Lower blood pressure might also signal reduced anxiety levels during birth. However, these devices did not influence obstetric and neonatal outcomes, according to our study. Owing to the paucity of research on wireless-enabled antepartum maternal-fetal monitoring, there is not enough data to compare our study results. Comprehensive studies with larger sample sizes are required to gather substantial information on this subject, especially to evaluate obstetric and neonatal outcomes more effectively.

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Obstet Gynecol. 2020 May;2(2):100101. doi: 10.1016/j.ajogmf.2020.100101. Epub 2020 Mar 17.

J Surg Med. 2025;9(5):67-70.
https://doi.org/10.28982/josam.7844

JOSAM

Research article
https://jsurgmed.com/

Journal of Surgery and Medicine

e-ISSN: 2602-2079

The association between surgery type and heart-specific mortality in male breast cancer

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Abstract

Background/Aim: Male breast cancer, while less prevalent than female breast cancer, remains a significant health concern for men. Heart-specific mortality presents a significant worry for male breast cancer patients, as treatment and underlying comorbidities may increase their risk for cardiovascular complications. The purpose of this study was to investigate the associations between the type of surgery and heart-specific mortality in male breast cancer patients.

Methods: Data were extracted from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) 17 tumor registry database. The study encompassed a total of 86 male breast cancer patients who succumbed to heart disease. Patients with missing data on key variables were excluded. We divided the patients into two groups based on the type of surgery they received: breast-conserving surgery (BCS) and mastectomy.

Results: The mean age of the BCS group was 78.9 years, while the mean age of the Mastectomy group was 74.7 years. The tumor was most commonly located in the center on both sides. There was no statistically significant difference in the ethnic composition of the groups. All patients in both groups were estrogen receptor (ER) positive. Grade 1 tumors were more prevalent in the BCS group, and Grade 3 tumors were more prevalent in the Mastectomy group. The survival rates did not significantly differ between the two types of surgeries.

Conclusion: This study suggests that the type of surgery (BCS or mastectomy) does not significantly affect heart-specific mortality in male breast cancer patients. For a deeper understanding of any additional factors impacting heart-related outcomes in this cohort, further research is required.

Keywords: male breast cancer, disease of heart, survival

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Ethics Committee Approval
As this study utilized de-identified data from the SEER database, which is publicly available and maintains patient anonymity, ethical approval and informed consent were not required.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 May 27

How to cite: Sanli AN. The association between surgery type and heart-specific mortality in male breast cancer. J Surg Med. 2025;9(5):67-70.

Introduction

When compared to breast cancer in females, male breast cancer is a rare but significant malignancy [1]. Breast-conserving surgery (BCS) and mastectomy are surgical options for treating male breast cancer [2]. Although the main goals of these operations are achieving local control and improving overall survival, it remains unclear how they may influence certain causes of mortality, such as heart-related deaths [3]. To optimize treatment options and enhance patient outcomes, it is essential to understand the relationship between the type of surgery and heart-specific mortality in male breast cancer patients [4].

This study aimed to investigate the relationship between the type of surgery and heart-specific mortality in male breast cancer patients. We aimed to ascertain whether the chosen surgical procedure impacts the risk of heart-related fatalities in this population. We utilized data from the SEER 17 tumor registry database, a comprehensive, population-based compilation of cancer cases across the United States maintained by the National Cancer Institute.

Materials and methods

The data were obtained from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) 17 tumor registry database, updated in November 2021. The information was extracted using the SEER*Stat 8.4.0.1 program. The starting point for SEER was set in 2010, as it began collecting information on HER2 status that year. Male breast cancer patients who died due to heart disease were selected for this study, with a total of 86 patients' data examined based on clinicopathological and oncological outcomes. Patients with unknown age, race, molecular subtype, grade, estrogen receptor (ER), progesterone receptor, Her2 status, stage, and surgery status were excluded from the analysis. Patient groups were determined based on the type of surgery performed: breast-conserving surgery (BCS) or mastectomy.

Statistical analysis

Categorical variables were compared using Pearson's chi-square test, Fisher's exact test, or Fisher Freeman Halton test, as appropriate. The Mann-Whitney U test was used to compare non-normally distributed continuous variables. Survival curves were created using the Kaplan-Meier method. The log-rank test was employed to compare survival outcomes among different patient subgroups. All tests carried out were two-sided, and P <0.05 was deemed statistically significant. Statistical analysis was executed using SPSS for Windows (version 22.0, SPSS Inc., Chicago, IL, USA).

Results

The demographic characteristics of the 86 male breast cancer patients who succumbed to heart disease are summarized in Table 1. The median age at diagnosis was 80 years (range 49–85 years). Nine patients underwent BCS, while 77 patients went through a mastectomy. The majority of patients were 80 years old or older. Notably, a significant decrease in the number of male breast cancer patients dying from heart disease was observed in 2018 and 2019. In terms of laterality, 40 patients had cancer in the right breast, and 46 had it in the left breast. The tumor was most commonly located centrally on both sides (Figure 1).

Table 1: Patient characteristics.

	n=86	BCS	Mastectomy	*P*-value
Age, mean (SD)	75.1 (10.11)	78.9 (10.01)	74.7 (10.01)	0.295a
Race				
White	72 (83.7%)	8 (88.9%)	64 (83.1%)	1b
Black	9 (10.5%)	1 (11.1%)	8 (10.4%)	
Other	5 (5.8%)		5 (6.5%)	
ER status				
Positive	86 (100%)	9 (100%)	77 (100%)	
PR status				
Positive	83 (96.5%)	9 (100%)	74 (96.1%)	1c
Negative	3 (3.5%)		3 (3.9%)	
Her2 status				
Positive	9 (10.5%)		9 (11.7%)	0.278d
Negative	77 (89.5%)	9 (100%)	68 (88.3%)	
Grade				
1	10 (11.6%)	3 (33.3%)	7 (9.1%)	**0.048b**
2	43 (50%)	5 (55.5%)	38 (49.4%)	
3	33 (38.4%)	1 (11.1%)	32 (41.6)	
Laterality				
Right	40 (46.5%)	3 (33.3%)	37 (48.1%)	0.494c
Left	46 (53.5%)	6 (66.7%)	40 (51.9%)	
Molecular subtype				
Luminal A	77 (89.5%)	9 (100%)	68 (88.3%)	0.278d
Luminal B	9 (10.5)		9 (11.7%)	
Stage				
1A	20 (23.3%)	4 (44.4%)	16 (20.8%)	0.467b
1B	3 (3.5%)	1 (11.1%)	2 (2.6%)	
2A	24 (27.9%)	3 (33.3%)	21 (27.3%)	
2B	18 (20.9%)	1 (11.1%)	17 (22.1%)	
3A	9 (10.5%)		9 (11.7%)	
3B	10 (11.6%)		10 (13%)	
3C	1 (1.2%)		1 (1.3%)	
4	1 (1.2%)		1 (1.3%)	
Survival (month)	35.1 (26.1)	31.8 (31.6)	35.5 (25.6)	0.810e

a: Mann-Whitney U, b: Fisher Freeman Halton, c: Fisher's Exact Test, d: Pearson Chi-Square, e: Kaplan Meier (Long rank)

Figure 1: Patients characteristics. A) year of diagnosis, B) age at diagnosis, C) tumor localization.

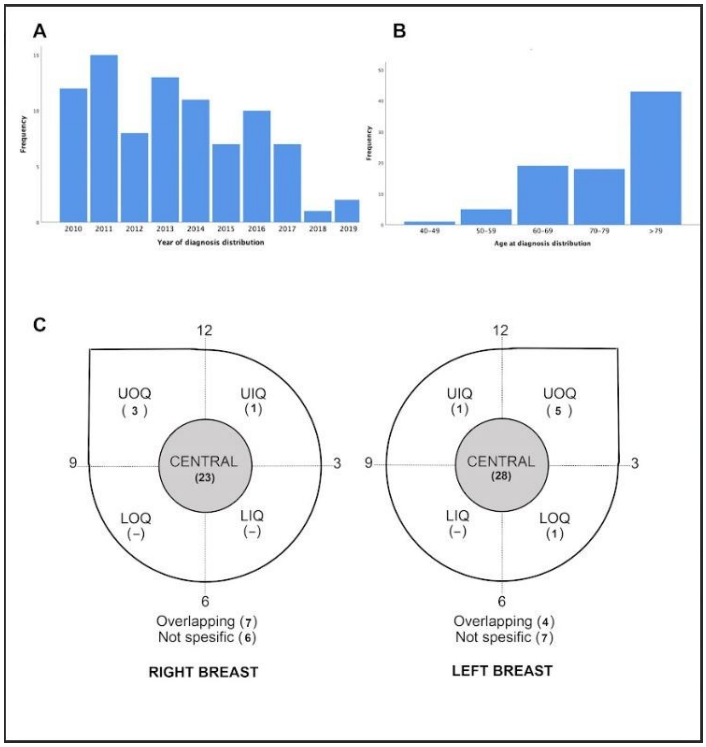


Table 1 outlines the clinicopathologic features of the patients and the results from subgroup tests. The average age was 78.9 (10.01) for the BCS group and 74.7 (10.01) for the Mastectomy group. Most of the patients were of white ethnicity, with whites accounting for 88.9% in the BCS group and 83.1% in the Mastectomy group. However, there was no statistically significant difference in ethnicity between the two groups.

All patients in both groups were ER positive. There were no progesterone receptor (PR) negative patients in the BCS

group, whereas in the Mastectomy group, the PR negativity rate was 3.9%. There were no HER2-positive patients in the BCS group, but 11.7% of patients in the Mastectomy group were HER2-positive.

Grade 1 (33.3% vs. 9.1%) was more common in the BCS group, while Grade 3 (11.1% vs. 41.6%) was more frequent in the Mastectomy group. The rate for Grade 2 was similar in both groups (55.5% vs. 49.4%). There was no significant difference in laterality (P=0.494).

Neither group presented with HER2-enriched or triple-negative cancer. In the BCS group, all patients were Luminal A, whereas in the Mastectomy group, 88.3% were Luminal A. All patients who underwent BCS were in the early stage, and 72.8% of patients who underwent mastectomy were also at this stage. However, there was no significant difference in the distribution of stages between these groups.

The average survival time was 35.1 (26.1) months. Notably, there was no significant difference in survival rates across the groups (P=0.810). The 5-year survival rate was slightly higher in the BCS group at 22.2% compared to 22.1% in the Mastectomy group (Figure 2).

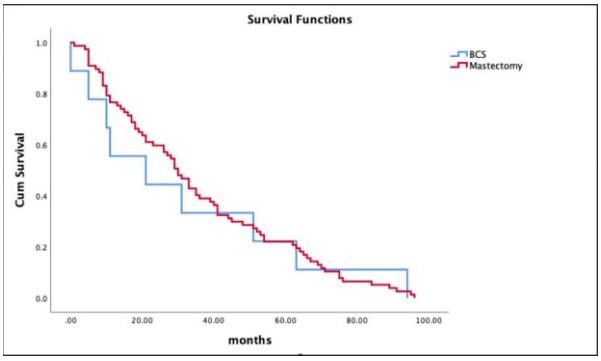
In the univariate regression analysis, race, ER status, PR status, HER2 receptor status, grade, laterality, stage, and molecular subtype were not identified as prognostic factors (Table 2).

Table 2: Cox proportional-hazard models.

	Univariate analysis		
	HR	**%95 CI**	***P*-value**
Race			
White	Reference		
Black	1.161	0.576-2.430	0.676f
Other	1.856	0.741-4.646	0.187f
PR status			
Positive	Reference		
Negative	1.290	0.405-4.110	0.667f
Her2 status			
Positive	Reference		
Negative	0.748	0.370-1.511	0.418f
Grade			
1	Reference		
2	0.497	0.246-1.007	0.052f
3	0.666	0.325-1.363	0.266f
Laterality			
Right	Reference		
Left	1.316	0.856-2.021	0.211f
Molecular subtype			
Luminal A	Reference		
Luminal B	1.337	0.662-2.702	0.418f
Stage			
1A	Reference		
1B	0.564	0.166-1.920	0.360f
2A	1.162	0.633-2.134	0.627f
2B	1.263	0.662-2.409	0.478f
3A	0.775	0.340-1.768	0.545f
3B	1.308	0.605-2.825	0.495f
3C	0.529	0.070-3.974	0.536f
4	92.407	5.612-1521.487	**0.002f**

f: Cox-regression analysis

Figure 2: Survival analysis by groups.



Discussion

The present study aimed to investigate the association between surgery type and heart-specific mortality in male breast cancer patients. The findings of our analysis indicate that whether BCS or mastectomy is performed, there is no significant difference in heart-specific mortality in this cohort.

Our results align with earlier research that discovered similar outcomes for overall survival between BCS and mastectomy in male breast cancer patients [5,6]. This suggests that in this patient population, long-term survival may not be primarily influenced by the surgical method. It is crucial to note that our study solely focused on heart-specific mortality and omitted important outcomes such as local recurrence rates and distant metastases.

The mean age at diagnosis in our study was aligned with the older age group that is frequently affected by male breast cancer [7]. The condition primarily affects the elderly, and consequently, the majority of patients in both the BCS and Mastectomy groups were 80 years of age or older [8]. An unexpected finding, which may warrant further investigation, is the reported reduction in the number of male breast cancer patients who died from heart disease in 2018 and 2019. This could be attributed to various factors, including improvements in cardiovascular care, changes in treatment protocols, or enhanced overall cancer management.

The BCS and Mastectomy groups displayed substantial differences, as evidenced by clinicopathological analysis. The BCS group had a higher prevalence of Grade 1 cancers, whereas the Mastectomy group had a higher prevalence of Grade 3 tumors. This suggests potential shifts in tumor biology and aggression between the two groups, which could influence treatment selection and long-term outcomes [9]. Despite these variations, there were no significant differences in survival rates between the BCS and mastectomy procedures.

It was interesting to note that all of the patients in both groups had estrogen receptor (ER) positive breast cancer, demonstrating a high frequency of hormone receptor-positive disease. This finding aligns with previous research [10–13] that highlighted hormone receptor positivity in the majority male breast cancer cases. Additional information about the molecular subtypes of male breast cancer was provided by the absence of PR negativity in the BCS group and some Her2 positivity in a few patients in the mastectomy group [14]. However, in our investigation, there was no significant relationship between the distribution of molecular subtypes and survival outcomes.

The lack of prognostic factors and substantial differences in survival rates among the analyzed variables underscore the necessity to explore new variables that might impact heart disease-related outcomes in male breast cancer patients. These factors might encompass genetic susceptibility, adjuvant treatments, cardiovascular comorbidities, treatment-related cardiotoxicity, lifestyle factors, and cardiovascular comorbidities [15,16]. The management of cardiovascular disease and other potentially influential variables should be carefully considered, in addition to surgical intervention, as part of a comprehensive multidisciplinary approach to patient care [17,18].

Limitations

It is important to acknowledge that our study has several limitations. First, the study's retrospective design, which relies on registry data, has inherent biases and constraints. Second, the slightly small sample size may have impacted our ability to identify minor variations among all types of surgeries. Moreover, the study did not consider additional crucial endpoints, such as local recurrence or distant metastases, focusing solely on heart-specific mortality. To corroborate our findings and gain a more comprehensive understanding of the relationship between the type of surgery and outcomes in male breast cancer patients, further research with larger sample sizes and extended follow-up periods is necessary.

Conclusion

Our research indicates that the type of surgery a male undergoes, whether BCS or mastectomy, has no significant impact on heart-specific mortality. This underscores the need for a comprehensive approach to managing male breast cancer, taking into account many aspects beyond the surgical procedure. To improve survival rates and outcomes for patients with male breast cancer, further studies are required to elucidate the complex relationships between breast cancer, surgical treatments, and cardiovascular outcomes.

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J Surg Med. 2025;9(5):71-73.
https://doi.org/10.28982/josam.8041

JOSAM

Case report
https://jsurgmed.com/

Journal of Surgery and Medicine

e-ISSN: 2602-2079

A rare encounter with cholecysto-colonic fistula: A comprehensive case study

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Abstract

Cholecysto-colonic fistula is a rare complication of calculous cholecystitis. It can also occur following previous surgeries, or in association with gallbladder carcinoma. Although the majority of patients remain asymptomatic, some may present with symptoms such as abdominal pain, vomiting, fever, jaundice, diarrhea, lower gastrointestinal bleeding, or sepsis. Diagnosis is challenging and typically requires a comprehensive diagnostic work-up or is incidentally made during surgery. This report presents a case involving an 84-year-old man with diabetes and hypertension, diagnosed with a spontaneous cholecysto-colonic fistula that mimicked acute cholecystitis. Diagnostic confirmation was achieved through imaging studies, including computed tomography and contrast-enhanced computed tomography. The patient underwent surgery which required conversion from a laparoscopic to an open approach due to extensive adhesions. The fistula was surgically removed, and the colonic defect was repaired. The patient's postoperative course was complicated by paralytic ileus and surgical site infection, but he recovered well and was discharged without further complications. Histopathological examination confirmed acute necrotizing cholecystitis. Cholecysto-colonic fistula remains a significant consideration in patients with recurrent cholecystitis and gastrointestinal symptoms. Early diagnosis and appropriate surgical intervention are crucial to prevent serious complications.

Keywords: cholecysto-enteric fistula, gallbladder, Mirrizzi syndrome, recurrent cholecystitis

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Informed Consent
The authors stated that the written consent was obtained from the patient presented with images in the study.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 May 9

Introduction

A cholecysto-enteric fistula is an uncommon complication of calculous cholecystitis, previous surgery, and gallbladder carcinoma [1]. Among all cholecysto-enteric fistulas, cholecysto-colonic fistula accounts for 8–26.5%, second only to cholecystoduodenal fistula, which makes up 75% [2]. Most patients show no symptoms and diagnosis is typically challenging. For symptomatic cases, surgical intervention is required [3]. Herein, we report a case of spontaneous cholecysto-colonic fistula, with clinical manifestations resembling acute cholecystitis.

How to cite: Rajkumar KS, Kuppusamy P. A rare encounter with cholecysto-colonic fistula: A comprehensive case study. J Surg Med. 2025;9(5):71-73.

Case presentation

An 84-year-old gentleman, a known diabetic and hypertensive, with no history of cholelithiasis, presented with a 10-day history of right upper abdominal pain, multiple episodes of nonbilious vomiting, and fever. He was not jaundiced and was hemodynamically stable. His physical examination revealed a distended abdomen and marked tenderness in the right hypochondrium without peritonitis. Routine blood investigations were insignificant. Initial evaluation with a plain computed tomography of the abdomen showed features of acute cholecystitis and a suspicious cholecysto-colonic fistula with hepatic flexure. These findings were then confirmed with a contrast enhanced computed tomography of the abdomen (Figure 1).

During surgery, the initial laparoscopic approach had to be converted into a right subcostal laparotomy due to extensive adhesions involving the gallbladder, hepatic flexure, and the greater omentum. Pericholecystic omental adhesions were separated through blunt dissection. A fistulous tract, which established a connection between the fundus of the gallbladder and the hepatic flexure was observed, and divided via blunt dissection. A difficult retrograde cholecystectomy was carried out. The defect in the hepatic flexure was primarily sealed in two layers (Figure 2A, 2B) using 3-0 PDS, following the excision of the defect margins (Figure 3).

Postoperatively, he was administered five days of parenteral antibiotics, which covered both aerobic and anaerobic organisms. He subsequently developed paralytic ileus and a surgical site infection, both of which were managed appropriately. On the eighth day following surgery, he was discharged without experiencing any complications. His histopathological report indicated acute necrotizing cholecystitis. He displayed no symptoms at his postoperative review, which took place two weeks after the surgery.

Figure 1: Contrast enhanced computed tomography abdomen showing pneumogallbladder (arrow mark).

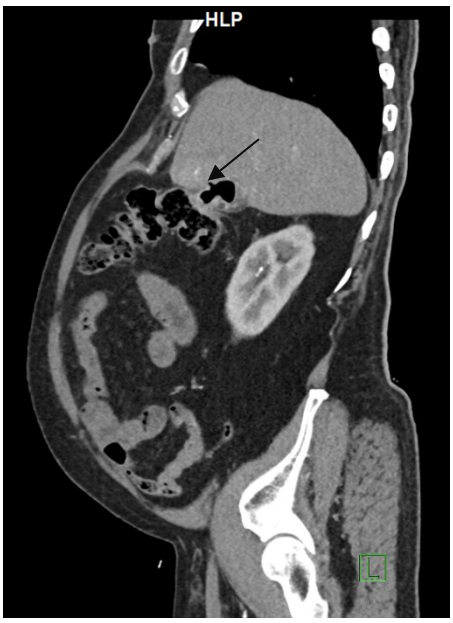


Figure 3: Excised fistula margin from the hepatic flexure.

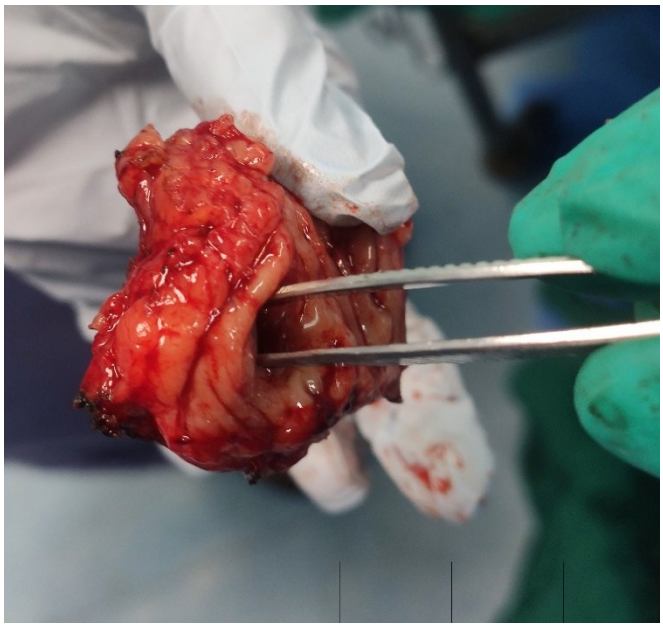
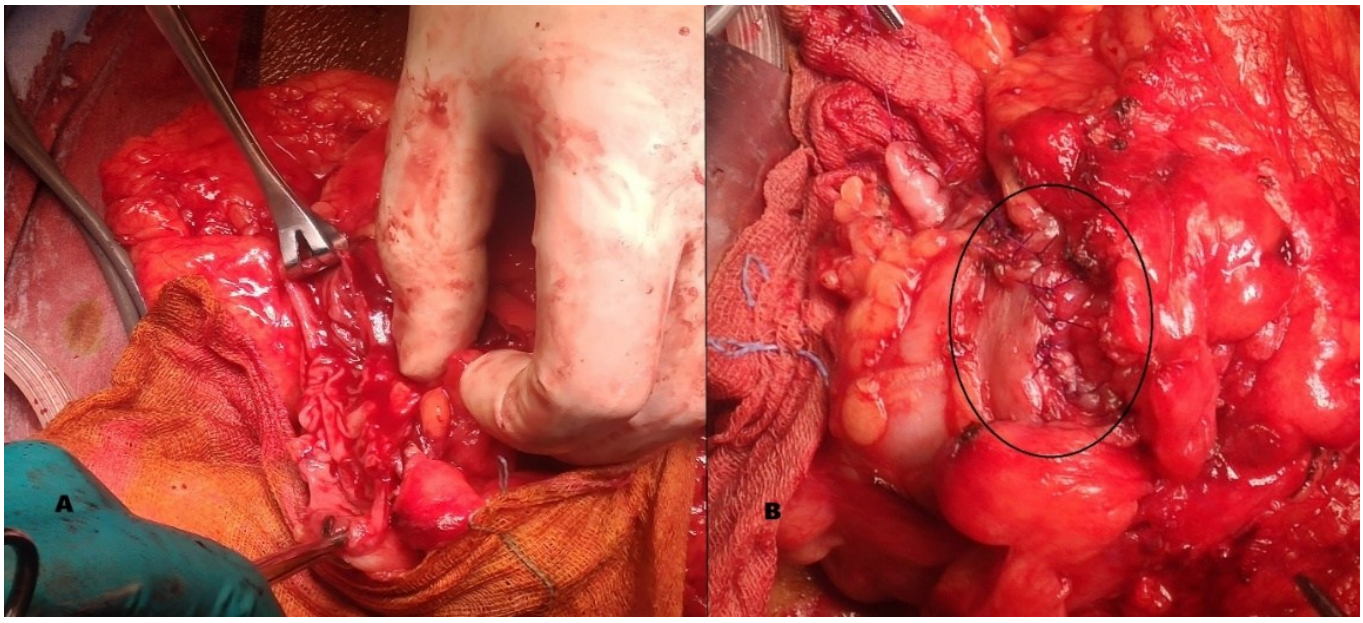


Figure 2: A: Defect in the hepatic flexure after excising fistula margin. B: Defect closed horizontally.



Discussion

Cholecysto-colonic fistula is an exceedingly rare outcome of calculous cholecystitis, with an incidence of 0.13% [4]. It is believed that the compression of the gallbladder wall by large gallstones, coupled with regular bouts of cholecystitis, can lead to dense adhesions. These, in turn, can result in erosion between the gallbladder and the adjacent viscus, thereby forming a fistula [5].

The preoperative diagnosis of cholecysto-colonic fistula is also difficult. Huang et al. [5] reported a preoperative diagnostic accuracy of 58.6%. Computed tomography is considered more accurate than ultrasonogram, while magnetic resonance cholangio-pancreatography is particularly beneficial if associated with choledocholithiasis or Mirrizzi syndrome. The following circumstances should raise suspicions of a cholecysto-colonic fistula presence: Repeated attacks of cholecystitis and suspicious imaging findings (thick-walled gallbladder, ill-defined border between gallbladder & bowel loops, pneumobilia, pneumogallbladder).

The surgical treatment usually involves cholecystectomy, followed by fistula closure and, occasionally, bowel resection. The surgery can be conducted using both laparoscopic and open methods. However, laparoscopic approaches are generally challenging due to dense adhesions and inflammation around the gallbladder. Therefore, a conventional open cholecystectomy with fistula excision often serves as the best option in challenging cases. Moreover, it is essential to include the fistulous part of the colonic wall in the resected specimen to rule out colonic carcinoma at the fistula site.

Therefore, patients diagnosed with cholecystitis, along with non-specific gastrointestinal symptoms such as diarrhea and lower gastrointestinal bleeding, should be suspected of having a cholecysto-enteric fistula, necessitating a thorough work-up.

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J Surg Med. 2025;9(5):74-77.
https://doi.org/10.28982/josam.8078

JOSAM

Case report
https://jsurgmed.com/

Journal of Surgery and Medicine

e-ISSN: 2602-2079

Sizable retrograde transtubal leakage of saline during bipolar hysteroscopic myomectomy: A potential cause of hypoxia

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Informed Consent
The authors stated that the written consent was obtained from the patient presented with images in the study.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2025 May 8

Abstract

This case report discusses a bipolar hysteroscopic myomectomy procedure for a type II FIGO submucous myoma using 0.9% saline as a distension medium. Following the successful excision of the myoma, a significant decrease in oxygen saturation was observed, confirmed by blood gas analysis, urgent X-ray, and echocardiography. Despite the absence of acidosis or pulmonary edema, emergency abdominal ultrasonography revealed a large volume of intraperitoneal fluid. Approximately one liter of intraperitoneal saline was drained during an emergency laparoscopic intervention, leading to a notable improvement in the patient's hypoxia. This case highlights the importance of considering retrograde transtubal leakage of saline as a potential cause of intraoperative hypoxia, particularly in patients undergoing advanced hysteroscopic procedures with suspected patent fallopian tubes.

Keywords: hysteroscopy, saline, hypoxia, fallopian tube, myomectomy

Introduction

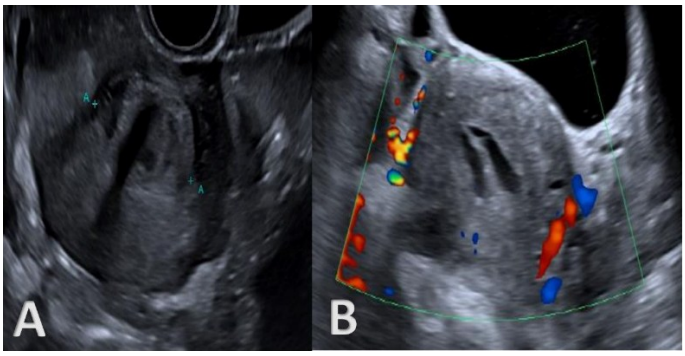
Saline is commonly used as an electrolyte-rich distension medium for bipolar or mechanical hysteroscopic surgery due to its isotonic nature, which eliminates the risk of hyponatremia or hypokalemia. However, its low viscosity can lead to mixing with blood, requiring higher infusion volumes for adequate visualization. Exceeding the maximum fluid deficit of 2500 mL in healthy individuals or 1500 mL in cardiac patients or those with comorbidities can result in complications such as left-sided heart failure, pulmonary edema, or even mortality [1]. Previous studies have primarily focused on calculating fluid outflow using suction bottles, urine output bags, and perineal bags, neglecting intraperitoneal leakage during endometrial cavity distension [2]. This case report highlights a significant retrograde transtubal leakage of saline into the peritoneal cavity, leading to severe intraoperative hypoxia during advanced hysteroscopic myomectomy.

How to cite: Darwish A, Zubeydi L, Darwish D, Dervis V, FF Mohamed, ML ElKhatib. Significant retrograde transtubal leakage of saline during bipolar hysteroscopic myomectomy: A potential cause of hypoxia. J Surg Med. 2025;9(5):74-77.

Case presentation

The patient, a 36-year-old woman, P (1+0), had a cesarean delivery six years ago during her previous marriage. She visited the outpatient department due to severe episodes of vaginal bleeding, particularly menorrhagia and dysmenorrhea, accompanied by colicky pain. Despite using oral contraceptive pills, she did not actively seek fertility. During the clinical assessment, she weighed 54 kg and did not exhibit any obvious signs of systemic bleeding. She was 158 cm tall with a waist circumference of 61 cm. A Type II FIGO submucous anterior wall myoma measuring 3.5 x 3 cm was identified through abdominal and vaginal ultrasonography (Figure 1-A). The recommendation was for her to undergo a hysteroscopic myomectomy instead of an open myomectomy. The patient was provided with detailed information about the benefits of a hysteroscopic myomectomy, taking into account the extensive experience of the senior surgeon (AD) in hysteroscopic intrauterine procedures spanning 34 years.

Figure 1: A: Preoperative transabdominal ultrasonography shows an anterior wall type II fibroid. B: Postoperative transabdominal ultrasonography (with Doppler) shows complete resection of the fibroid with intrauterine hypoechogenic shadow at site of resection (mild bleeding).



She underwent evaluation and preparation for hysteroscopic intrauterine surgery during the follicular phase after receiving approval from her insurance provider. She was assessed at the anesthesia clinic and classified as ASA class 1. Her initial vital signs were within normal limits, with a blood pressure of 130/80, heart rate of 80 bpm, and SpO2 of 98% on room air. Following a detailed explanation using a uterine model, the patient and her husband signed a comprehensive consent form outlining all potential complications of the procedure, including the need for laparoscopy or laparotomy in case of perforation or other issues. After obtaining approval from both her insurance company and the Institutional Review Board (IRB #23125), the patient was scheduled for the surgery. She was informed that the procedure would be performed using bipolar resectoscopy with 0.9% saline distending media due to its established safety profile compared to monopolar resectoscopy. The patient received 200 micrograms of misoprostol sublingually six hours before the procedure to aid in cervical dilatation, as previously recommended. Although spinal anesthesia was recommended, the patient opted for general anesthesia, which was induced with 100 mg of fentanyl, 150 mg of propofol, and 35 mg of esmeron administered intravenously. A size 7.5 mm endotracheal tube was inserted and secured for airway protection, and standard monitoring devices were applied. Anesthesia was maintained with sevoflurane 1%, a mixture of oxygen and air (50%:50%), and mechanical ventilation in volume control mode. Intravenous Ringer Lactate infusion was limited to 300 ml/h.

A diagnostic hysteroscopy was performed to locate and determine the size of the myoma. The procedure took two minutes. Cervical dilatation up to Hegar's 10 was done to insert a bipolar resectoscope (Olympus bipolar resectoscope, Hamburg, Germany). A resectoscopic myomectomy was carried out (Figure 2-A) with a concurrent intramuscular injection of one ampoule of ergometrine to aid in the myoma's protrusion into the endometrial cavity. Saline was infused using a mechanical distension media machine, and the procedure lasted 20.30 minutes. The machine was not automated, and the flow rate was chosen arbitrarily without specifying fluid pressure. There was an overall fluid deficit of 2500 mL, calculated by adding the suction unit amount, urine outflow, and the amount collected in the perineal bag.

The anesthesiologist observed a gradual decline in vital signs without a clear explanation. EtCO2 decreased from 40 to 25 mmHg, SpO2 dropped from 100% to 84%, blood pressure was 70/35 mmHg, heart rate increased to 100 bpm, and airway pressure rose to 38 cmH2O. As a precaution, the anesthesiologist administered a 40 mg IV bolus of furosemide, but there was no improvement in hypoxia. The O2 flow was increased to 100%. Fortunately, the procedure was completed at that time (Figure 2-B), allowing the observation of tightness and distention in the abdomen when the drapes were pulled back. A code blue was called immediately. Chest examination, blood gas analysis, urgent X-ray, and echocardiography all indicated no signs of pulmonary edema or acidosis, as confirmed by the pulmonologist and cardiologist. An urgent abdominal ultrasound by a radiologist revealed a significant amount of free intraperitoneal fluid, which could explain the hypoxia. Following an urgent diagnostic laparoscopy that confirmed the presence of free intraperitoneal fluid (Figure 3-A), there was a significant improvement in hypoxia after aspirating at least one liter of clear free fluid (Figure 3-B). SpO2 increased to 95%, BP to 100/65 mmHg, and heart rate to 90–100 bpm.

The patient was placed on mechanical ventilation for approximately thirty minutes. Sugammadex 100 mg was administered to reverse the effects of a muscle relaxant, and the patient was extubated once she demonstrated effective breathing. Her oxygen saturation levels (SpO2) ranged between 96% and 92%. Subsequently, she was transferred to the high care unit (HCU) and provided with 10 L/min of 100% oxygen via a face mask. Postoperative chest CT scan and X-ray results were normal. A thin intrauterine hypoechogenic shadow suggestive of some bleeding was detected on the second day through abdominal ultrasonography, confirming complete excision of the myoma (Figure 1-B). Two days later, she was discharged from the hospital in good health.

Figure 2: A: Bipolar resectoscopic excision of the fibroid using slicing technique. B: fibroid tissues after resection.

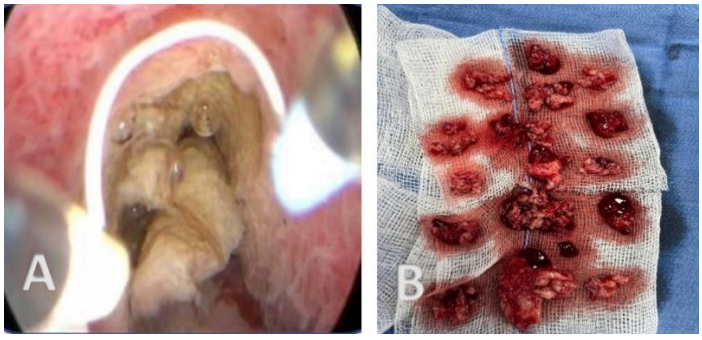
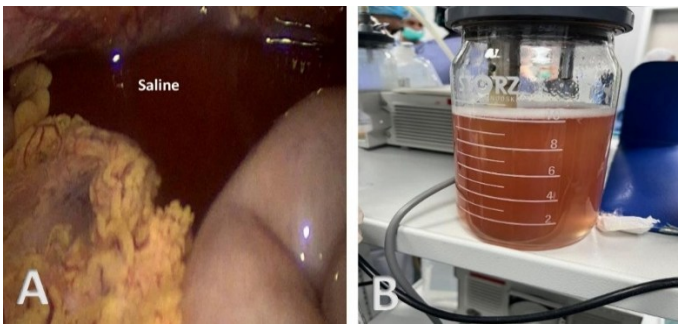


Figure 3: A: Diagnostic laparoscopy revealed free intraperitoneal saline. B: Suction of about one liter of 0.9% saline.



Discussion

Bipolar electrosurgery is known for its safety compared to monopolar electrosurgery. One of the key advantages of bipolar electrosurgery is the avoidance of electrolyte-free solutions, which can lead to risks such as hyponatremia and systemic consequences. This is particularly beneficial in advanced intrauterine procedures like hysteroscopic myomectomy. Previous studies have shown that bipolar resectoscopy is superior to monopolar resectoscopy [3]. Since then, we have been using bipolar electrosurgery with saline distension media. While 0.9% saline is generally safe, excessive infusion can potentially lead to fluid overload, resulting in complications such as pulmonary edema, left-sided heart failure, or even death, especially in complex hysteroscopic surgeries like type II or III myomectomy. The miscibility of saline with blood may require the surgeon to use a larger volume for better visualization, contributing to the risk of saline fluid overload.

Safety considerations for intrauterine surgery include selecting an appropriate size and type of myoma (type II), completing the procedure efficiently, opting for saline in bipolar resectoscopy instead of glycine in monopolar resectoscopy, and scheduling the procedure in the immediate postmenstrual period to minimize fluid absorption. Therefore, when the patient experienced sudden hypoxia, the surgeon considered the possibility of fluid overload and took appropriate action.

Due to the direct connection of the normally patent fallopian tubes with the endometrial cavity and the increased intrauterine pressure during hysteroscopic surgery, most women with patent tubes undergoing hysteroscopy experience accumulation of distension media in the pelvis (RTL). The lack of routine use of intraoperative ultrasonography and the short duration of hysteroscopic procedures often result in incomplete exploration of this inevitable intraoperative fluid leakage, which could potentially lead to fluid overload or dissemination of cancerous cells [4]. It is advisable to perform hysteroscopic intrauterine surgeries in the postmenstrual phase, as demonstrated in this case, as premenstrual individuals tend to have higher rates of fluid passage and speed [5]. Several factors influence RTL during hysteroscopy, including the procedure duration, distension media flow rate, intrauterine pressure (IUP), type of surgery (e.g., myomectomy), lesion size, and residual myometrial thickness (RMT). A lower RMT may require more time for excising a type II or III myoma, as illustrated in this type II myoma case. The intratubal opening pressure has been reported as 75 mmHg [6], suggesting that RTL may occur if IUP is ≥75 mmHg. Studies have indicated that RTL occurs when IUP exceeds 80 mmHg [7], although a study involving 164 patients undergoing diagnostic hysteroscopy found no correlation with IUP [8]. Another study on 64 cases undergoing hysteroscopy alone or with laparoscopy did not show a relationship between IUP and RTL. However, the limited sample size and diverse study population in these studies underscore the variability of results. Intraabdominal pressure (IAP) typically ranges from 0 to 5 mmHg, with a slight increase (10–15 mmHg) maintaining cardiac index. A moderate increase in IAP (15–25 mmHg) during laparoscopy may necessitate surgical decompression, while an IAP ≥25 mmHg defines abdominal compartment syndrome requiring decompression [9]. Ensuring the safety of endoscopic procedures and providing simultaneous laparoscopic supervision for advanced hysteroscopic intrauterine procedures is crucial. Laparoscopic monitoring allows for aspiration of intraperitoneal fluid collections and enhances surgical safety to prevent inadvertent uterine perforation. Alternatively, intraoperative ultrasound surveillance, particularly during prolonged intrauterine procedures, is emphasized in this case study. Availability of an ultrasound machine in the operating room for intermittent monitoring of intrauterine surgeries and final checks is essential.

We reported aspiration of over one liter of intraperitoneal saline, which is more than double the volume reported in a previous study [10]. This can be attributed to several risk factors in this case for RTL. The lack of automatic hysteromat usage led to an inaccurate assessment of the flow rate and IUP. The nature of the lesion as a type II myoma penetrating the myometrium, along with the inevitable prolonged procedure duration, was an additional factor. The patient's thin build and small waist circumference indicated a small peritoneal cavity, increasing the likelihood of hypoxia due to limited space. The patient's loss of consciousness during the procedure, as she opted for general anesthesia over spinal anesthesia, delayed the recognition of hypoxia. Lastly, since she was not trying to conceive and only presented with abnormal uterine bleeding and pain, it is likely that both of her fallopian tubes were patent.

Conclusion

RTL of saline, which can occur during advanced hysteroscopic surgery, should be anticipated, especially if the patient experiences unexplained hypoxia. It is important to consider this when calculating fluid deficit in advanced hysteroscopic procedures. Utilizing sonographic or laparoscopic monitoring during advanced hysteroscopic surgery can help prevent unexpected intraoperative complications. Increased awareness among gynecologists and anesthesiologists about potential hysteroscopic complications can lead to early detection and timely interventions for optimal outcomes. Experienced hysteroscopists are encouraged to conduct further research on RTL following various types of intrauterine hysteroscopic surgeries and to compare outcomes based on patient and surgical factors.

Acknowledgments

We are grateful for the hard work put in by the CODBLUE team and for the patient's willingness to allow the publication of her case.

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