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Incidence of In-Hospital Postoperative Bleeding in Women Undergoing Breast Cancer Surgery: A Multicenter Retrospective Cohort Study from 26 German Hospitals Between 2019 and 2024

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Abstract

Background/Objectives: The incidence of postoperative bleeding following breast surgery varies considerably in the literature. The present study therefore examines various surgical treatment approaches and their potential associations with risk factors using real-world data. Methods: This multicenter retrospective cohort study analyzed anonymized hospital data from the IQVIA hospital database, which comprises 49 German hospitals, of which 26 contributed eligible breast cancer surgery hospitalizations, between January 2019 and January 2024. Hospitalizations of women aged 18 years or older who underwent breast cancer surgery were included, and postoperative bleeding and hematoma were defined using International Classification of Diseases, Tenth Revision (ICD-10) codes T81.0 or D62. The primary analysis was a multilevel (mixed-effects) logistic regression model with hospital as a random intercept. Results: The study included 13,137 hospitalizations of 11,754 women from 26 hospitals. Postoperative bleeding or hematoma occurred in 3.7% of hospitalizations, ranging from 1.6% to 13.6% across hospitals with at least 10 hospitalizations. Mastectomy (6.2% vs. 2.8% after partial resection; odds ratio (OR) 2.08, 95% confidence interval (CI) 1.69–2.55) and long-term use of anticoagulants (7.1%; OR 2.05, 95% CI 1.50–2.78) were associated with a higher incidence of bleeding. No association was detected with age, tumor localization, prior chemotherapy, comorbidities or lymph node involvement. Bleeding risk varied significantly between hospitals (intraclass correlation 6.5%, median odds ratio 1.58). Results were consistent for bleeding requiring reoperation or transfusion and in sensitivity analyses. Conclusions: In patients undergoing breast cancer surgery, long-term use of anticoagulants and mastectomy were associated with an increased risk of postoperative bleeding or hematoma formation, whereas no association was detected for age, tumor site, prior chemotherapy, or common comorbidities. Variability between hospitals may reflect differences in case-mix, coding practice, or perioperative management and warrants further investigation.

Keywords: breast cancer surgery; postoperative bleeding; hematoma; mastectomy; anticoagulant therapy; risk factors

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1. Introduction

Breast cancer is the most common malignancy among women in Western countries, with approximately 2.3 million new cases recorded worldwide in 2022 [1]. Surgical resection,

either in the form of breast-conserving therapy (BCT) or mastectomy with or without reconstructive surgery [2], is a central component of breast cancer treatment. Despite surgical techniques and perioperative management strategies being largely standardized, there remains a clinically relevant risk of perioperative complications. Among these, postoperative bleeding and hematoma formation are particularly frequently reported [3].

Postoperative bleeding, with or without hematoma formation, is a complication of breast surgery that can lead to wound healing disorders, prolonged hospital stays and/or repeat surgical interventions [4]. Major postoperative complications, including bleeding events, have been associated with an impaired prognosis and a reduced probability of survival [5,6].

The incidence of postoperative bleeding after breast surgery varies considerably in the literature. A comprehensive Japanese database analysis of 477,108 patients reported an incidence of 1.5% [3]. A retrospective cohort study from Finland involving 4712 patients undergoing BCT reported rates ranging from 0.3% to 1.1% [7]. By contrast, an Australian prospective study examining microsurgical autologous tissue reconstruction reported postoperative hematoma requiring surgical revision in 5.8% of patients [8]. Danish population-based registry studies reported reoperation for bleeding within 14 days after breast cancer surgery in approximately 2.5% of women [9,10].

These studies also identified various risk factors for postoperative bleeding. Certain surgical procedures, particularly total mastectomy, have been associated with an increased risk of bleeding compared to breast-conserving therapy and reconstructive procedures, especially flap-based reconstructions such as autologous tissue reconstructions [3,7,8,11–14]. Comorbidities including arterial hypertension, anemia, obesity, diabetes mellitus, cardiovascular disease, and chronic organ diseases have been reported as potential risk factors [3,5,6]. Premedication with antithrombotic agents, particularly anticoagulants such as heparin and antiplatelet agents, has also been associated with an increased risk of bleeding [7,15,16].

Previous studies have reported the incidence of postoperative bleeding following surgical treatment for breast cancer under specific study conditions, resulting in relevant limitations. Consequently, the current data situation remains incomplete. In particular, it is questionable whether the findings of the Japanese study by Konishi et al. can be transferred unrestrictedly to European healthcare systems [3]. The Finnish analysis included a relatively small number of cases and was based on a single-center cohort [7]. Similarly, the study by Phan et al. focused exclusively on hematomas after microvascular breast reconstruction and cannot be extrapolated to other surgical techniques [8]. In particular, large-scale European data that jointly integrate surgical procedures, patient-related risk factors, and hospital-level variation in bleeding risk are still lacking.

This study aims to investigate the in-hospital incidence of postoperative bleeding, with and without hematoma formation, following breast cancer surgery in a real-world dataset of German hospitals. The retrospective analysis considers breast-conserving therapy as well as mastectomy with and without primary reconstruction, and potential risk factors associated with postoperative bleeding.

2. Materials and Methods

2.1. Data Source

This multicenter retrospective cohort study was based on data from the IQVIA hospital database, which contains information on over two million hospitalizations from 49 hospitals across Germany between 1 January 2019 and 31 January 2024. The participating hospitals represent all levels of care, including primary, standard, maximum, and university hospitals; they provide their data voluntarily and are not a random sample of German hospitals. Data were routinely collected and submitted to the Institute for the Hospital Remuneration

System (InEK) in a standardized electronic format in accordance with Section 21 of the German Hospital Compensation Act (KHEntgG). All patient records were anonymized prior to data transfer to ensure full compliance with German data protection regulations. Each record represents one hospitalization; stays of the same patient can be linked only within the same hospital. This database has previously been used in several peer-reviewed studies evaluating postoperative complications and in-hospital outcomes [17,18]. Because patients were identified from routine records and followed for the in-hospital occurrence of the outcome, the design is best classified as a retrospective cohort study.

2.2. Study Population

Hospitalizations of women aged 18 years or older with a main diagnosis of breast cancer (International Classification of Diseases, Tenth Revision [ICD-10]: C50) or carcinoma in situ of the breast (D05) and at least one Operations and Procedures Key (OPS) code for partial resection (5-870.2, 5-870.6, 5-870.9, 5-870.a) or mastectomy (5-872, 5-874, 5-877) were included. Hospitalizations in which more than one type of breast surgery was coded were excluded. Of the 49 hospitals, 39 recorded at least one hospitalization with a main diagnosis of C50 or D05 and 26 performed eligible breast cancer surgery during the study period; the remaining hospitals had no eligible cases. The unit of analysis was the hospitalization. The selection process is shown in Figure S1 and the complete code list in Table S1.

2.3. Study Outcome and Variables

The primary outcome was the occurrence of in-hospital postoperative bleeding or hematoma during the index hospitalization, as defined by the ICD-10 code T81.0 (“bleeding and hematoma complicating a procedure”) or D62 (“acute posthemorrhagic anemia”). D62 was included because, in hospitalizations for breast cancer surgery, acute posthemorrhagic anemia results from blood loss, and some bleeding events were coded as D62 without T81.0. As neither code grades severity, a secondary outcome was defined as bleeding or hematoma with an additional OPS code for reoperation or wound revision (5-983, 5-881, 5-892, 5-896) or transfusion (8-800) during the same stay. Baseline variables included age, type of surgery, tumor localization (carcinoma in situ, nipple or areola, central portion, various quadrants of the breast, axillary tail, overlapping lesions, and unspecified sites), presence of lymph node or distant metastases, history of chemotherapy, and major comorbidities such as diabetes mellitus, obesity, hypertension, and long-term use of anticoagulant medication (Z92.1). Additional variables were breast reconstruction (implant-based or autologous), oncoplastic reduction or mastopexy, axillary surgery (lymphadenectomy or sentinel or single lymph node excision), bilateral disease or surgery, long-term use of other drugs including antiplatelet agents (Z92.2), and annual hospital volume of breast cancer surgery. All variables were derived from codes, and the absence of a code was interpreted as absence of the condition. Age, hospital, and length of stay (LOS) were available for all hospitalizations, so no hospitalization was excluded because of missing values.

2.4. Statistical Analysis

Descriptive analyses were used to summarize patient characteristics, LOS, and the cumulative incidence of bleeding or hematoma overall and at each hospital, shown for hospitals with at least 10 hospitalizations to ensure stable estimates. The primary analysis was a multilevel (mixed-effects) logistic regression model including all predefined covariates as fixed effects and hospital as a random intercept, estimated by maximum likelihood with Laplace approximation (PROC GLIMMIX). Between-hospital variation was quantified by the variance of the random intercept, the intraclass correlation coefficient (ICC), and the median odds ratio (MOR), and the significance of the hospital-level variance was assessed with

a likelihood-ratio test. The results are presented as odds ratios (ORs) with 95% confidence intervals (CIs). Supplementary analyses comprised a single-level multivariable logistic regression, an extended model including the additional surgical and hospital variables, models for the secondary outcome and for T81.0 alone, and sensitivity analyses restricted to the first hospitalization per woman, to hospitals with at least 10 hospitalizations, and excluding hospitals with high bleeding proportions. Unless stated otherwise, all 13,137 hospitalizations were included in each model. A two-sided *p*-value below 0.05 was considered statistically significant. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC, USA).

3. Results

3.1. Baseline Characteristics of Study Patients

A total of 13,137 hospitalizations of 11,754 women from 26 hospitals were included (Figure S1); 1223 women had more than one eligible hospitalization. The mean age was 62.4 years (standard deviation [SD] 13.5), with almost a third of patients aged 70 years or older. Partial resection was the most common surgical approach, performed in 72.4% of hospitalizations, followed by mastectomy in 27.6%. Breast reconstruction was coded in 5.1% and axillary lymphadenectomy in 16.0%. Tumors were most frequently located in the upper-outer quadrant of the breast, while carcinoma in situ accounted for 9.9% of cases. Lymph node metastases were present in 20.9%, and distant metastases in 4.6%. A previous history of chemotherapy was recorded in 16.1%. Hypertension was the most common comorbidity, affecting approximately one third of patients, whereas diabetes mellitus, obesity, and long-term anticoagulant use occurred less frequently. The mean LOS was 4.3 days (SD 3.2), 3.5 days after partial resection and 6.4 days after mastectomy (Table 1, Table S7).

Table 1. Baseline characteristics of the study sample.

Variable	N, % or Mean (SD)
Hospitalizations (women)	13,137 (11,754)
Age (mean, SD)	62.4 (13.5)
Age group	
Age < 50 years	2322 (17.7)
Age 50–59 years	3269 (24.9)
Age 60–69 years	3430 (26.1)
Age ≥ 70 years	4116 (31.3)
Type of surgery	
Partial resection	9509 (72.4)
Mastectomy	3628 (27.6)
Additional procedures	
Breast reconstruction (any)	671 (5.1)
Implant-based reconstruction	575 (4.4)
Autologous reconstruction	99 (0.8)
Oncoplastic reduction or mastopexy	324 (2.5)
Axillary lymphadenectomy	2099 (16.0)
Sentinel or single lymph node excision only	8085 (61.5)
Bilateral disease or surgery	640 (4.9)
Breast cancer diagnosis (tumor site)	
Carcinoma in situ	1306 (9.9)
Nipple and areola	106 (0.8)
Central portion	803 (6.1)
Upper-inner quadrant	1447 (11.0)

Table 1. *Cont.*

Variable	N, % or Mean (SD)
Lower-inner quadrant	855 (6.5)
Upper-outer quadrant	5261 (40.0)
Lower-outer quadrant	1279 (9.7)
Axillary tail	11 (0.1)
Overlapping lesion	1709 (13.0)
Unspecified part of breast	360 (2.7)
Tumor spread and treatment history	
Presence of lymph node metastasis	2740 (20.9)
Presence of distant metastasis	604 (4.6)
History of chemotherapy	2119 (16.1)
Comorbidities	
Diabetes mellitus	995 (7.6)
Obesity	679 (5.2)
Hypertension	4533 (34.5)
Long-term (current) use of anticoagulants	800 (6.1)
Long-term (current) use of other drugs incl. antiplatelet agents	402 (3.1)
Length of stay in days, mean (SD)	4.3 (3.2)
Length of stay in days, median (IQR)	4 (2–5)

Proportions of hospitalizations given in % unless otherwise indicated. SD: standard deviation; IQR: interquartile range. Additional procedures are not mutually exclusive.

3.2. Incidence of Bleeding and Hematoma

Overall, postoperative bleeding or hematoma occurred in 488 hospitalizations (3.7%). The cumulative incidence was notably higher after mastectomy (6.2%) and in hospitalizations with overlapping breast lesions (6.2%), axillary tail or unspecified sites (5.4%), and a history of chemotherapy (4.7%). The highest rate was observed among women receiving long-term anticoagulant therapy (7.1%), whereas the lowest incidence was found after partial resection (2.8%). Bleeding requiring reoperation or transfusion was coded in 289 hospitalizations (2.2%). Hospitalizations with bleeding were longer than those without (median 5 vs. 3 days after partial resection and 8 vs. 6 days after mastectomy; Table S7). Of the 488 events, 405 were coded as T81.0 (61 of them together with D62) and 83 as D62 only; the share of events coded as D62 only varied between hospitals (Table S5).

As shown in Figure 1, the proportion of hospitalizations with postoperative bleeding or hematoma varied considerably between hospitals performing breast cancer surgery, ranging from 1.6% to 13.6% among the 20 hospitals with at least 10 hospitalizations. Events and denominators for all hospitals are given in Table S5.

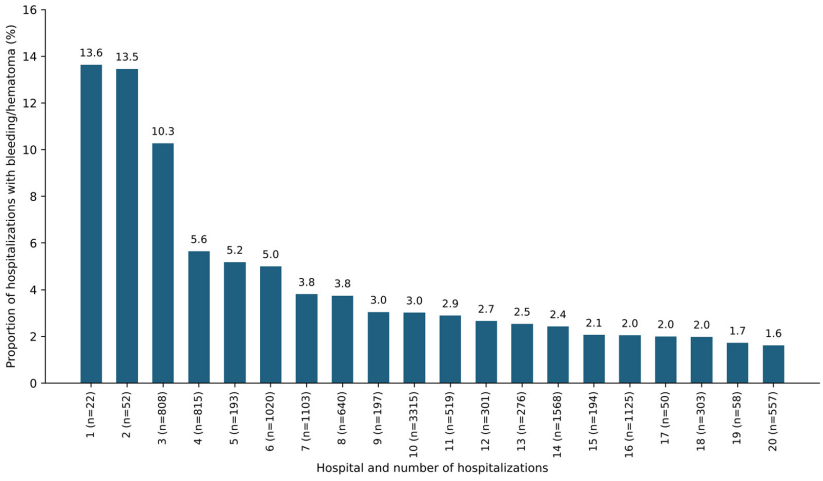

Figure 1. Proportions of breast cancer surgery hospitalizations with bleeding and hematoma by hospital (hospitals with at least 10 hospitalizations).

3.3. Factors Associated with Postoperative Bleeding and Hematoma

In the multilevel logistic regression model (Table 2), mastectomy was associated with a higher risk of bleeding or hematoma than partial resection (OR 2.08, 95% CI 1.69–2.55), as was long-term use of anticoagulant medication (OR 2.05, 95% CI 1.50–2.78). No association was detected for age, tumor localization, lymph node or distant metastases, history of chemotherapy (OR 1.19, 95% CI 0.93–1.53), diabetes mellitus, obesity, or hypertension.

Table 2. Association of predefined variables with bleeding and hematoma in breast cancer surgery hospitalizations (multilevel logistic regression).

Variable	Proportion of Hospitalizations with Bleeding and Hematoma (%)	Odds Ratio (95% CI) *	*p*-Value
Total	3.7		
By age group			
Age < 50 years	3.9	Reference	
Age 50–59 years	3.4	0.96 (0.72–1.29)	0.784
Age 60–69 years	3.1	0.85 (0.63–1.15)	0.293
Age ≥ 70 years	4.4	0.90 (0.66–1.21)	0.471
By primary surgery			
Partial resection	2.8	Reference	
Mastectomy	6.2	2.08 (1.69–2.55)	<0.001
By breast cancer diagnosis			
Carcinoma in situ	2.9	Reference	
Nipple and areola	3.8	1.23 (0.42–3.57)	0.707
Central portion	3.7	1.04 (0.63–1.73)	0.870
Upper-inner quadrant	3.9	1.34 (0.87–2.05)	0.187
Lower-inner quadrant	3.6	1.14 (0.70–1.87)	0.600
Upper-outer quadrant	3.1	1.01 (0.70–1.46)	0.964
Lower-outer quadrant	3.0	0.98 (0.61–1.56)	0.918
Overlapping lesion	6.2	1.29 (0.86–1.93)	0.224
Axillary tail or unspecified part of breast	5.4	1.44 (0.80–2.57)	0.223
By tumor spread and treatment history			
Presence of lymph node metastasis	4.6	1.14 (0.91–1.43)	0.249
Presence of distant metastasis	6.0	1.06 (0.72–1.56)	0.759
History of chemotherapy	4.7	1.19 (0.93–1.53)	0.163
By comorbidity			
Diabetes mellitus	5.0	1.17 (0.85–1.61)	0.336
Obesity	3.2	0.81 (0.51–1.27)	0.356
Hypertension	4.3	1.11 (0.90–1.38)	0.328
Long-term (current) use of anticoagulants	7.1	2.05 (1.50–2.78)	<0.001

* Multilevel logistic regression with hospital as random intercept, adjusted for age group, primary surgery type, breast cancer diagnosis, presence of lymph node metastasis, presence of distant metastasis, history of chemotherapy, and comorbidities. Random-intercept variance 0.229 (standard error 0.108), intraclass correlation coefficient 6.5%, median odds ratio 1.58. CI: confidence interval.

The risk of bleeding or hematoma varied significantly between hospitals (random-intercept variance 0.229, standard error 0.108; likelihood-ratio test $\chi^2 = 70.3$, $p < 0.001$), corresponding to an ICC of 6.5% and a MOR of 1.58.

3.4. Additional and Sensitivity Analyses

In the single-level logistic regression, prior chemotherapy (OR 1.27, 95% CI 1.00–1.61) and overlapping lesions (OR 1.50, 95% CI 1.01–2.23) were of borderline significance, but

these associations were not confirmed after accounting for hospital clustering (Table S2). In the extended model, breast reconstruction was additionally associated with bleeding (OR 1.75, 95% CI 1.21–2.51), whereas axillary surgery, bilateral disease, long-term use of other drugs including antiplatelet agents, and hospital volume were not (Table S3). The associations of mastectomy and anticoagulant use were consistent for bleeding requiring reoperation or transfusion, for T81.0 alone (Table S4), for the first hospitalization per woman (n = 11,754), for hospitals with at least 10 hospitalizations, and after exclusion of the large hospital with a high bleeding proportion (hospital 3 in Figure 1; mastectomy OR 2.16, 95% CI 1.74–2.69; anticoagulants OR 1.79, 95% CI 1.27–2.51). After this exclusion, the between-hospital variance decreased (ICC 2.9%, MOR 1.35) but remained statistically significant (likelihood-ratio test $\chi^2 = 12.6$, $p < 0.001$) (Table S6).

4. Discussion

4.1. Main Findings

This study found an overall in-hospital cumulative incidence of postoperative bleeding or hematoma of 3.7%, which lies within the range reported in the previous literature [3,7,8,11–13]. Bleeding was most strongly associated with long-term anticoagulant use (7.1%) and mastectomy (6.2%). By contrast, no association was detected for age, prior chemotherapy, tumor localization, common comorbidities (e.g., diabetes mellitus or obesity), or indicators of local or systemic tumor spread. Furthermore, bleeding risk varied substantially between hospitals; in the multilevel model, the between-hospital variance was statistically significant and independent of measured patient- and procedure-level factors.

4.2. Interpretation of Results

The differences in bleeding incidence between mastectomy and breast-conserving therapy are consistent with international findings. Konishi et al. reported that mastectomy, axillary dissection, longer operating times, and more complex procedures like reconstruction with tissue expanders or flaps are associated with higher bleeding rates [3,14]. Seth et al. noted that postoperative bleeding often originates from highly vascularized areas such as the chest wall muscles or axillary structures, which are more exposed during mastectomy procedures [11]. Danish population-based studies using reoperation for bleeding within 14 days likewise identified mastectomy and older age as predictors, with an overall reoperation risk of about 2.5% [9,10], which is close to the 2.2% of bleeding with reoperation or transfusion in our data; unlike these studies, we detected no association with age. In the extended model, breast reconstruction was additionally associated with bleeding, consistent with reports of higher hematoma rates after immediate reconstruction [11,12]. Mastectomy patients stayed longer in hospital, which increases the opportunity for in-hospital coding; however, LOS was also longer after mastectomy in hospitalizations without bleeding, and the association was similar for bleeding requiring reoperation or transfusion.

The increased incidence of bleeding in patients receiving long-term anticoagulant therapy is consistent with previous studies. Tamminen et al. demonstrated that continuing antithrombotic therapy perioperatively increases the risk of bleeding and hematoma formation by approximately two to four times, although the absolute risk remains low [7]. Recent analyses have shown the clinical balance between bleeding risk and venous thromboembolism following breast cancer surgery [14]. As only the code for long-term anticoagulant therapy (Z92.1) was available, the type, dose, and perioperative interruption or resumption of anticoagulation could not be assessed. While anticoagulation therapy increases the risk of bleeding, adequate thromboprophylaxis remains essential in high-risk patients. Implant-based reconstructions are associated with a lower risk of bleeding, whereas longer surgical

procedures and autologous reconstructions may increase the risk of both bleeding and thromboembolism [14].

Prior chemotherapy was associated with bleeding only in the single-level model, and this association was not confirmed after accounting for hospital-level clustering. Possible mechanisms such as chemotherapy-related thrombocytopenia, platelet dysfunction, or vascular endothelial damage were not examined in the present study [15,16], and prior chemotherapy should therefore not be regarded as an independent risk factor on the basis of our data.

Overlapping breast lesions showed a higher crude bleeding proportion (6.2%), but no independent association was detected in the multilevel model. One possible hypothesis is that multifocal or overlapping tumor presentations necessitate larger resection volumes and more technically demanding procedures [19,20]. However, data specifically addressing bleeding risk in patients with overlapping breast lesions remain limited and require further investigation.

In this study, no association was detected between diabetes mellitus, hypertension, or obesity and postoperative bleeding. Obesity was coded in only 5.2% of hospitalizations, far below its population prevalence, which suggests under-coding in administrative data; this finding should therefore be interpreted with caution. Other analyses have identified obesity (body mass index over 25.0 kg/m^2) as a risk factor for bleeding [3,21]. In a Danish nationwide cohort, women with type 2 diabetes had a higher 30-day risk of complications after breast cancer surgery, including surgical-site complications such as reoperation for bleeding or infection [22]. Large database analyses suggest that comorbidities such as cardiovascular disease, liver disease, or anemia may be more consistent predictors of bleeding risk, whereas metabolic disorders may primarily affect wound healing or infection risk rather than acute postoperative bleeding [3,5,7,12,13,23].

The considerable variation in bleeding rates between hospitals may reflect differences in case-mix, coding practice, and documentation as well as differences in perioperative management, standard operating procedures, postoperative monitoring, and surgical techniques; the present data do not allow these explanations to be distinguished. Postoperative bleeding and hematoma formation after breast surgery range between 1% and 7% internationally, which is consistent with the findings of this study [3,7,8,11–13]. The between-hospital variation was not explained by hospital volume; it was largely driven by one large hospital with a high bleeding proportion but remained statistically significant after its exclusion. The share of events coded as D62 only also differed between hospitals, and the between-hospital variation was smaller for T81.0 alone (ICC 4.0%; Table S4), which suggests that coding practice contributes to the observed variation.

4.3. Clinical Implications and Need for Future Research

The risk factors identified support the importance of preoperative risk assessment, structured patient counseling, and individualized perioperative management strategies. However, these findings should be interpreted with caution due to the retrospective study design. Patients undergoing mastectomy, particularly with reconstruction, and those receiving anticoagulant therapy may be considered to be in a higher-risk group and may benefit from closer postoperative monitoring. As most bleeding events occur within 12–24 h postoperatively, as described in the literature [7,8], focused monitoring during this critical period may facilitate early detection and intervention.

Preventive perioperative strategies deserve further consideration. Tranexamic acid has been associated with decreased postoperative bleeding in breast surgery [4]; however, its impact on heterogeneous real-world populations requires further study. As the present database did not capture tranexamic acid use, potential confounding or protective effects

could not be assessed. Future studies incorporating standardized tranexamic acid protocols may help clarify its role in routine clinical practice.

If inter-hospital differences partly reflect perioperative practice, internal quality improvement measures, such as standardized bleeding prevention protocols, uniform drainage strategies, and structured postoperative monitoring pathways, could reduce variability and improve patient outcomes. Although there is no direct support in the literature for these measures in the context of breast surgery, the systematic review by Harji et al. demonstrates that protocolized care pathways are associated with reduced hospital length of stay and postoperative mortality [24].

Since no association was detected for age or typical internal comorbidities in the present study, future research should focus on surgical parameters, tumor biology, and pharmacological influences in a structured manner. Prospective, ideally multicenter studies including reconstructive procedures are needed to confirm these associations, better characterize relevant risk factors, and develop evidence-based strategies.

4.4. Strengths and Limitations of the Study

A major strength of this study is the large multicenter sample, which facilitates a comprehensive assessment of the frequency and patterns of postoperative bleeding in current clinical practice. The use of routinely documented healthcare data reduces memory distortion and reflects real-world treatment processes, despite the limited depth of data. The multicenter design and inclusion of hospitals at different levels of care enhance the study's external validity and transferability compared to single-center cohorts. Uniform national coding rules (ICD-10 German Modification [ICD-10-GM] and OPS) allow the same case definitions to be applied in all hospitals, although coding practice may still differ between institutions. The large sample size permits the analysis of rare events such as postoperative bleeding and the identification of potential risk constellations.

Limitations of the study include its retrospective secondary data-based design, which excludes access to detailed intraoperative information (e.g., surgery time, surgeon experience, intraoperative blood loss, drains) and laboratory parameters (e.g., platelet count, coagulation values), as well as information on smoking status, type, timing and dosage of anticoagulant therapy, antiplatelet therapy (only partly captured by Z92.2), endocrine therapy, tranexamic acid, tumor stage, body weight, and prior bleeding of the patients. Administrative coding may result in misclassification and does not capture bleeding severity or anatomical location. The ICD-10 coding records all bleeding events, regardless of clinical relevance or severity, and does not distinguish intraoperative from postoperative bleeding; we therefore added a secondary outcome requiring reoperation or transfusion. Only the index hospitalization was analyzed, so bleeding after discharge or in other hospitals was not captured; in an exploratory analysis, 80 hospitalizations (0.6%) without in-hospital bleeding were followed by a readmission with T81.0 to the same hospital within the following month. The retrospective design limits causal inference, allowing the identification of statistical associations only rather than causal relationships. In addition, the unavailability of operative details, laboratory parameters, and information on perioperative anticoagulation management, together with likely under-coding of comorbidities such as obesity in administrative data, may have resulted in residual confounding.

While variations in bleeding rates between hospitals suggest that structural and procedural differences, such as institutional specialization, years of experience, surgical volume, and historical complication rates, may modify outcomes, these factors could not be examined in detail, and differences in case-mix and coding practice are equally possible explanations. The participating hospitals are not a random sample of German hospitals, which may limit generalizability. To partly address this, hospital-level clustering was incorporated

as a random effect in a multilevel model; however, the specific structural and procedural factors underlying the observed institutional variation could not be identified from the available data and warrant dedicated investigation. Regardless of these limitations, the present study delivers a comprehensive overview of postoperative bleeding after breast surgery in Germany and generates hypotheses for further prospective research.

5. Conclusions

The present study found that the in-hospital cumulative incidence of bleeding or hematoma formation in women undergoing breast cancer surgery was 3.7%. Long-term anticoagulant use and mastectomy were associated with an increased risk of bleeding, whereas no association was detected for age, prior chemotherapy, tumor site, or common comorbidities. The considerable variability between hospitals may reflect differences in case-mix, coding practice, or institutional perioperative procedures. High-risk patients may benefit from structured risk evaluation and standardized perioperative management.

Supplementary Materials: The following supporting information can be downloaded at https://www.mdpi.com/article/10.3390/diseases14120452/s1: Figure S1: Selection of the study population; Table S1: Codes used to define surgery types, additional procedures, outcomes, and covariates; Table S2: Single-level multivariable logistic regression (all 13,137 hospitalizations, 488 events); Table S3: Extended multilevel model including additional surgical and hospital variables (13,137 hospitalizations, 488 events, 26 hospitals); Table S4: Secondary outcome (bleeding or hematoma with reoperation or transfusion) and bleeding defined by T81.0 alone; Table S5: Bleeding events and denominators by hospital and diagnosis code; Table S6: Sensitivity analyses (multilevel logistic regression with hospital as random intercept); Table S7: Length of stay (days) by type of surgery and bleeding.

Author Contributions: Conceptualization, L.R.; methodology, L.R., J.S., and K.K.; validation, K.K., J.S., and M.K.; writing—original draft preparation, L.R.; writing—review and editing, J.S., M.K., and K.K.; formal analysis, L.R. and K.K.; investigation, L.R. and K.K.; supervision, M.K. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: These data in the database are relatively anonymous. This assessment is based on the relative anonymity concept, as can be seen from Recital 26 of the EU General Data Protection Regulation (GDPR) and the European Court of Justice decision (judgment of 26 April 2023—T-557/20). In the data sets made available to IQVIA, personal identifiers have been removed by third parties as trustees or by software-supported measures in the participating hospitals, by encryption, so that re-identification by IQVIA is practically impossible. According to the GDPR (Recital 26) and the German Federal Data Protection Act (Bundesdatenschutzgesetz, BDSG § 27), research using anonymous data does not involve identifiable individuals and therefore does not require informed consent or approval by an ethics committee. As no directly or indirectly identifiable data were available to the authors at any time, ethics approval was not required for this observational study.

Informed Consent Statement: This study used data from the IQVIA hospital database, which contains only anonymized hospital administrative data. According to the EU General Data Protection Regulation, research using anonymized data does not involve identifiable individuals and therefore does not require informed consent.

Data Availability Statement: The data used in this study are subject to strict privacy and confidentiality requirements and therefore cannot be made publicly available. Legal restrictions prohibit the sharing of the raw data with third parties.

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Conflicts of Interest: K.K. is an employee of IQVIA, which owns the database used in this study. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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