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Indeterminate Surgical Margins after Partial Nephrectomy: Results from the Cancer Registry of Norway

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Abstract

Objectives: To determine the predictors and incidence for indeterminate surgical margins (ISMs) following partial nephrectomy (PN) and to assess associated clinical outcomes. **Patients and Methods:** A retrospective analysis of 524 patients from the Cancer Registry of Norway who underwent PN between January 2014 and December 2015, with follow-up in 2021. Univariate and multivariate analysis were utilized to identify risk factors, while survival plots were employed to assess local recurrence, metastasis and overall survival. **Results:** ISMs occurred in 24 patients (5%). Hospitals performing < 10 PNs/year and non-university hospitals had higher risk of ISMs (7.6%) compared to university hospitals (2.4%) and those performing > 30 PNs/year (3.3%). Fuhrmann grade and number of histological sections emerged as significant risk factors, with ISMs in 8.3% of patients with Fuhrmann grade 1 and 10.8% in > 10 histological sections compared to 3.6% in <10 sections. The hazard ratios for Local recurrence with ISMs were 3.65 (p = 0.238) and 18.14 (p = 0.021) with univariate and multivariate analysis. **Conclusion:** ISMs is an uncommon finding following PNs. Low surgical volume, the use of more than 10 histological sections, Fuhrmann grade 1 and treatment at non-university hospitals are risk factors for ISMs. Patients with ISMs have a higher risk for local recurrence and should be followed more closely than those with negative margins.

Keywords

Indeterminate Surgical Margins, Undetermined Margins, Local Recurrence,

Partial Nephrectomy, Metastasis, Survival

1. Introduction

Partial nephrectomy (PN) is a widely accepted surgical approach for the management of small renal masses, aiming to preserve renal function while achieving complete tumor resection. The EAU guidelines currently recommend PNs in T1 tumors and some T2 tumors when technically feasible [1].

Despite its benefits, positive surgical margins (PSMs) can occur in a subset of patients undergoing PN, raising concerns about oncological outcomes and the need for adjuvant therapy. Most studies report PSM in 2% - 8% of PNs [2]-[4]. In some cases, the margin described in the pathology report cannot be adequately evaluated for cancer involvement, and is therefore defined as an indeterminate surgical margin. This might occur due to technical or biological factors [5].

Despite extensive research on positive surgical margins, indeterminate surgical margins following partial nephrectomy remain poorly characterized in the literature. The reason could be the very low incidence in other published cohorts and the choice of other authors to omit these cases to simplify statistical analysis.

Several studies have reported a correlation between PSMs and local tumor recurrence after PN [6] [7]. The presence of PSMs indicates a higher likelihood of residual disease in the area surrounding the surgical margin. There are however, conflicting results whether PSMs poses a higher risk of metastasis or increases mortality [6]-[8].

The EAU guidelines currently recommend to intensify follow-up in patients with PSMs after PNs, but no guidelines are available for the management of ISMs. In our previous study [6], we created a patient database following PNs and assessed recurrence. Within this cohort, we identified a subgroup of patients with ISMs, which are further analyzed in this article.

This study aims to determine the incidence of ISMs following PNs and assess their clinical implications on oncological outcomes. Additionally, it seeks to investigate the factors contributing to ISMs by comprehensively analyzing various potential determinants collected from the Norwegian cancer registry.

2. Patients and Methods

The Norwegian Cancer Registry is considered to be of high quality, offering comprehensive and reliable data on cancer incidence, treatment, and outcomes in Norway. By law, all new cases of cancer are required to be reported to the population-based Cancer Registry of Norway (CRN). The registry database employs a high-quality tool that sends reminders to various departments to submit missing reports; thus, the completeness rate is very close to 100% [9]. However, like any registry or database, the Norwegian Cancer Registry may have limitations and challenges that can affect data quality. The registry did not include data on pa-

tients with benign tumours, and no patients with a proven benign histology after PN were registered in our study.

From the CRN data of more than 2,100,000 cancer cases, datasets for all 1668 patients with RCC (ICD-10 code C64), from 2014 to 2015, were extracted from the primary database in 2021. Of these, 1337 were surgically treated and 543 patients who underwent PN remained within the dataset. Two authors manually performed quality assurance of all CRN data used in the study, including re-evaluation of all histopathology reports. During this process, 19 patients with missing data for important variables were excluded. The final study population consisted of 524 patients, and their demographic, tumour-related, histology-related, and 5-year follow-up data were transferred to an anonymised database for subsequent analysis.

The analysed variables included age at diagnosis, sex, tumour characteristics, such as size and consistency (solid/cystic), number (uni/multifocality), surgery date and type (open/laparoscopy/robot-assisted), hospital volume, morphology type and grade, pT stage, presence of tumour necrosis or capsule invasion, surgical margin status, presence of local recurrence (LR) or metastasis, and death date and cause. Since the CRN only includes histologically proven cancer, this study did not record recurrence or metastasis diagnosed clinically or on imaging, but was not proven by biopsy. We defined so histologically proven recurrence as clinically significant for the patient's prognosis, since a biopsy is mostly performed to decide the optimal management for patients who are candidates for active treatment.

The CRN does not register data about the patient's status (e.g., Charlson comorbidity index, Eastern Cooperative Oncology Group performance status, previous surgery, solitary kidney, or body mass index) or nephrometry scores to assess tumour complexity. None patient had N+ stage disease or underwent lymphadenectomy concomitant with PN.

Hospital volume corresponding to each case was categorized as follows from the data for the number of procedures performed during the two-year observation period: low volume, ≤10; intermediate volume, 11 - 20; high volume, 21 - 30; and very high volume, >30 procedures/year. The lower limit for the very-high-volume group was arbitrarily determined based on the presumed volumes at major academic hospitals in Norway. For analysis and presentation purposes, we grouped the pT stage and Fuhrman grade into three groups as follows: pT1a, pT1b, and pT2 + pT3a and grades 1, 2, and 3 + 4, respectively. LR and ME were defined by the onset of neoplasms with identical histological patterns on the previous tumour resection bed or other organs, respectively.

3. Statistical Analysis

For all continuous variables differences across all three categories where tested using ANOVA. Assumptions of normality were checked using Q-Q plots of residuals and Homogeneity was tested using Levenes test of Equality of Variances. For the variables age Welchs homogeneity correction was applied due to slight

violation of homogeneity (p = 0.04). For the variables time to recurrence and Tumour-size, neither normality or homogeneity assumptions were met and the Kruskal-Wallis test was applied instead. For all categorical variables chi-square test of association were conducted.

To assess what predicts the outcome of ISM a generalized linear model with a multinomial categorical family was used in comparison to positive or negative. In the model ISMs was chosen as the reference category, and assumptions of multicollinearity and influential outliers were assessed. Predictor variables in the model were added based on our theoretical idea that histological section category and hospital volume interact to predict indeterminate status. Additional variables and interaction terms were added based on our descriptive analyses and maintained if they improved the fit of the model as evaluated by the Bayesian Information Criterion. Preliminary testing showed for all models the variance inflation factor (VIF) was below <1.22 indicating low degree of multicollinearity. No influential outliers were found as assessed by Cooks distance. Based on prediction models we conducted mediation models using structural equation model (SEM) in the statistical software JASP.

Survival analysis with Kaplan Meier curves were employed to assess local recurrence, metastasis and overall survival.

4. Results

The population characteristics are detailed in Table 1. The cohort consisted of 72% males (median age, 64 years; interquartile range [IQR], 54 - 79 years). Most tumours were solid (89.1%) and unifocal (96.9%) with a median [IQR] tumour diameter of 2.5 cm [1.8, 3.2 cm]). Of the surgeries, 42% were robot-assisted, 36.6% were laparoscopic, and 12.6% were open, while more than three-quarters were performed in intermediate- (40.8%) and high-volume (26.7%) hospitals.

Table 1. Clinical and oncological features of the population.

Variable	Overall (n = 524)
Age (years)	
Median [IQR]	64 [54 - 70]
Gender	
Man	378 (72.1%)
Woman	146 (27.9%)
Tumor size (cm)	
Median [IQR]	2.5 [1.8 - 3.2]
Tumor type	
Solid	467 (89.1%)
Cystic	57 (10.9%)
Tumor focality	
Unifocal	508 (96.9%)

Continued

Multifocal	16 (3.1%)
Surgical approach	
Open	66 (12.6%)
Laparoscopic	192 (36.6%)
Robot assisted	220 (42.0%)
Unknown	77 (14.7%)
Hospital Volume	
≤10 procedures/year	79 (15.1%)
11 - 20 procedures/year	214 (40.8%)
21 - 30 procedures/year	140 (26.7%)
>30 procedures/year	91 (17.4%)
pTstage	
pT1a	447 (85.3%)
pT1b	62 (11.6%)
pT2 + pT3a	16 (3.1%)
Histology	
Clear Cell	366 (69.8%)
Papillary	108 (20.6%)
Other	50 (9.5%)
Fuhrman grade	
1	58 (11.1%)
2	314 (59.9%)
3 + 4	130 (24.8%)
Unknown	22 (4.2%)
Tumor necrosis	
Yes	56 (10.7%)
No	392 (74.8%)
Unknown	76 (14.5%)
Capsule Infiltration	
Yes	20 (3.8%)
No	427 (81.5%)
Unknown	77 (14.7%)
Surgical Margins	
Negative	440 (84.0%)
Positive	60 (11.5%)
Undetermined	24 (4.6%)
Follow-up (months)	
Median [IQR]	81 [75 - 88]

Continued

Local recurrence	
Yes	18 (3.4%)
No	506 (96.6%)
Time to local recurrence (months)	
Median [IQR]	35 [24 - 56]
Metastasis	
Yes	17 (3.2%)
No	507 (96.8%)
Time to metastasis (months)	
Median [IQR]	18 [13 - 42]
Death	
Yes	70 (13.4%)
No	454 (86.6%)
Cause of death	
Kidney Cancer	13 (18.6%)
Other Cancer	22 (31.4%)
Other Cause	29 (41.4%)
Unknown	6 (8.6%)
Histological Section	
<5 slides	298 (56.9%)
5 - 10 slides	166 (31.7%)
>10 slides	37 (7.1%)
Unknown	23 (4.4%)
Hospital Status	
University Hospital	296 (56.5%)
Non-University Hospital	228 (43.5%)

IQR = interquartile range.

Histological features included a predominantly pT1a stage in almost 85% patients, clear cell type in nearly 70% of cases, and Fuhrman grade 2 in 60% cases. Tumour necrosis and capsule infiltration were observed in 10.7% and 3.8% of patients, respectively.

Among the cohort 24 patients (5%) exhibited ISM and 60 (11%) had positive margins. Surgical volume showed an inverse correlation with the risk of ISM; hospitals performing < 10 PNs/year had 7.6% risk compared to 3.3% in those performing > 30 PNs/year.

Fuhrmann grade emerged as a significant risk factor in both univariate and multivariate analysis, with ISMs occurring in 8.3% of the patients in the Fuhrmann grade 1 cohort compared 1.5% in the group with Fuhrmann grade 3 + 4.

The use of more than 10 histological sections was also identified as a significant risk factor, with ISMs occurring in 10.8% of cases with more than 10 histological

section compared to 3.7% and 3.6% in the groups with less than 10 sections.

Furthermore, university hospitals exhibited a lower incidence of ISM (2.4%) compared to non-university hospitals (7.6%).

The hazard ratio (HR) for Local recurrence with positive margins was 19.78 ($p < 0.001$) and 55.42 ($p < 0.001$) with univariate and multivariate analysis, respectively. HR for ISMs were 3.65 ($p = 0.238$) and 18.14 ($p = 0.021$) with univariate and multivariate analysis, respectively. Nearly 13% of the patients died during the follow-up period, and RCC was the cause of death in 18.6% of the patients. No statistical difference could be seen between the three types of surgical margins in terms of overall survival.

ISMs were a significant predictor for local recurrence on multivariate cox regression (HR 18.14, CI 1.55 - 212.79, $p = 0.021$), but not in univariate analysis (HR 3.65, CI 0.43 - 31.22, $p = 0.238$).

ISMs were not significant predictors for metastasis or overall survival on univariate (HR 1.56, CI 0.20 - 11.98, $p = 0.671$) nor multivariate cox regression (HR 4.81, CI 0.48 - 48.71, $p = 0.183$).

Tests of differences between categories of margins found differences related to age ($F = 3.55$, $p = 0.04$), Time of occurrence (Kruskall-Wallis = 6.82, $p = 0.03$), Surgery-type ($Chi^2 = 16.06$, $p = 0.01$), section category ($Chi^2 = 24.97$, $p = 0.01$), local recurrence ($Chi^2 = 25.77$, $p \leq 0.01$), total recurrence ($Chi^2 = 17.76$, $p \leq 0.01$) and hospital experience ($Chi^2 = 11.93$, $p \leq 0.01$).

Multinomial Regression-Results

The best fitting multinomial logistic regression to predict the occurrence of ISMs included number of histological sections, surgical volume and hospital status as either university or non-university (Table 2). The odds ratio of being categorized as indeterminate compared to negative and positive increased significantly when the setting was a non-university hospital by 5.05 and 20.29, respectively. Likewise, the odds ratio of being categorized as indeterminate compared to negative and positive increased significantly when the number of sections increased by 1.68 and 3.49, respectively. Furthermore, the odds ratio of ISM compared to positive margins increased significantly by 4.13 as hospital volume decreased. However, for negative relative to ISMs hospital volume was not significantly associated with increased odd ratio.

Table 2. Multinomal regression showed increased probability of indeterminate margins with high number of histological section, low surgical volume and non-university hospital status.

	OR	95% CI		p-value
		Lower	Upper	
Negative -> Indeterminate				
Histological section amount	1.68	1.12	2.50	0.01
Surgical volume	1.68	0.74	3.85	0.21

Continued

Hospital Status	5.05	1.52	16.94	0.008
Positive -> Indeterminate				
Histological section amount	3.49	1.91	6.42	<0.001
Surgical Volume	4.13	1.53	11.02	0.004
Hospital Status	20.28	4.80	84.77	<0.001

5. Discussion

Few studies have specifically addressed the phenomenon of uncertain or indeterminate surgical margins following partial nephrectomy. A large recent retrospective study [10] published in 2026 identified 2916 cases of indeterminate margins, corresponding to a 0.62% incidence within a national U.S. database. In multivariable analyses, indeterminate margins were associated with a 38% increased risk of death compared with negative margins and demonstrated outcomes intermediate between negative and positive margins. In contrast, our study identified a statistically significant increase in local recurrence but not overall survival. However, given the substantially larger study population in the referenced analysis, our cohort may have been underpowered to detect a survival difference. In that database, indeterminate margins were defined as cases in which margin status was not reported or could not be classified as positive or negative. A similar limitation applies to our study, as the underlying causes of indeterminate margins are likely heterogeneous and not fully captured by registry data. Future studies would benefit from detailed qualitative review of histopathological reports by dedicated genitourinary pathologists to better characterize the mechanisms underlying indeterminate margin classification.

Consistent with our observed incidence, a Canadian study [3] reported a prevalence of unknown surgical margins of 5.4%; however, the clinical significance and associated risks of this finding were not evaluated. Interestingly, the large U.S. study [10] suggested that their reported incidence of 0.62% may be underestimated due to variability in pathological reporting practices.

A recent retrospective study [11] demonstrated that positive surgical margins after partial nephrectomy were associated with a significantly increased risk of recurrence, whereas submillimeter negative margins (<1 mm) showed outcomes comparable to wider margins, suggesting that minimal margin width may be oncologically sufficient. It is likely that some pathologists may classify submillimeter negative margins as indeterminate, while others report them as negative, reflecting variability in pathological interpretation.

We observed an association between a higher number of histological sections and ISM. The variability in section number is likely multifactorial; however, it most plausibly reflects differences in pathology practice, while responses to intralaboratory diagnostic uncertainty and tumor complexity may contribute to a lesser extent.

A large amount of histological sections might lead to a more thorough examination with better quality. However, more histological sections can also give the pathologist more opportunities to be uncertain which could in part explain the association. Another explanation might be that in cases of doubt of the surgical margin, the pathologist might extract more histological sections retrospectively.

The size of each histological section was not specified, so the number of sections alone does not fully indicate the amount of tissue examined. Large format section (LFS) which are also called macrosections, allows for visualization of the entire tumour specimen in one plane along with the surgical margin [12]. LFS are generally believed to give a more extensive evaluation of the surgical margin. However, not all laboratories use this method because it is perceived as more costly and time consuming. We speculate that the cohorts in our study with a low number of sections include more LFS, unfortunately this information was not available to us.

It is possible that a pathology department with more volume and experience are less in doubt, which in turn decreased the incidence of uncertain surgical margins. If this is the case, a high number of histological sections could be viewed as a poor indicator of quality. Despite experience and skill, we believe it is unlikely that the surgical margin with can be classified with certainty as positive and negative in all cases. As such, it seems reasonable that some histological reports should classify the margin as uncertain in order to give the patient the most appropriate follow up.

In our investigation, we found that hospitals with lowest volumes were roughly twice as prone to having uncertain marginal statuses compared to their highest-volume counterparts. However, the data in **Table 3** fail to significantly capture this trend due to limitations inherent in the general linear model analysis. Nonetheless, our findings strongly suggest that low hospital volume poses a significant risk factor for indeterminate surgical margins. We observed an inverse relationship between surgical volume and the risk of indeterminate margins, yet we were unable to pinpoint a specific volume threshold associated with this risk. This suggest better oncological results when PNs are centralized, as shown in previous studies, [13] [14] where PSMs occurred in 9.6% and 11.8% in low-volume hospitals, compared to 2.6% and 4.6% in high-volume hospitals. The large U.S. study [10] further supports this association, demonstrating an odds ratio of 1.82 for indeterminate margins in non-academic facilities.

Table 3. Summarizing OR for ISMs for the different predictors in univariate and multivariate analysis.

Variable	OR Univariate	95% CI		p	OR Multivariate	95% CI		p
		lower	upper			lower	upper	
Sex								
Female (Ref)	Ref.				Ref.			
Male	0.52	0.23	1.18	0.12	0.97	0.37	2.54	0.96
Age	1.01	0.98	1.05	0.48	1.01	0.97	1.05	0.57

Continued

Hospital volume								
<10 PNs/year	Ref.							
10 - 20 PNs/year	0.68	0.28	1.67	0.4	1.27	0.43	3.71	0.67
>20 PNs/year	0.47	0.14	1.57	0.22	2.12	0.27	16.53	0.47
Histological Sections								
<5 sections (Ref)	Ref.							
5 - 10 sections	0.89	0.32	2.47	0.83	0.94	0.32	2.73	0.9
>10 sections	2.17	0.57	8.23	0.25	3.68	0.84	16.14	0.08
Unknown	6.04	1.89	19.26	**0.002**	11.18	2.55	48.95	**0.003**
Fuhrman grade								
Grade 1 (Ref.)	Ref.							
Grade 2	0.61	0.21	1.73	0.35	0.59	0.19	1.84	0.36
Grade 3 + 4	0.18	0.03	0.95	**0.04**	0.08	0.01	0.54	**0.009**
Unknown	0.52	0.06	4.78	0.57	0.5	0.05	5.01	0.55
Hospital Status								
University Hospital	Ref.							
Non-University	3.32	1.36	8.11	**0.008**	4.69	1.12	19.73	**0.03**

The correlation between surgical volume and ISM prevalence suggests that centers with a high incidence of ISMs could benefit from targeted training of uropathology services provided by high-volume centers.

Fuhrman grade was found to be a significant risk factor for indeterminate surgical margins on both univariate and multivariate analysis. Notably, cancers with the lowest Fuhrman grade had the highest risk for indeterminate surgical margins. The cohorts with lower Fuhrman grade also had smaller tumours, which may have appeared clinically less aggressive, leading to the choice of enucleation and resection with smaller surgical margins. In some cases, the Fuhrman grade is known preoperatively which might prompt the surgeon to take more generous margins in high-grade cases. However, we do not believe this factor alone explains our finding, as a previous Norwegian study [15] reported that only 8.4% of surgically treated patients had undergone a prior biopsy.

Several studies have reported a correlation between PSMs and local tumour recurrence after PN [6] [7] [13]. However, when nephrectomy or repeat PN are performed due to PSMs, only a small percentage of patients (6.9%) actually harbor residual malignancy [16]. There are conflicting results regarding whether PSM causes and increased risk of metastasis or reduces overall survival [4] [8] [17], with most studies reporting no statistical significance.

Because we found uncertain surgical margin status to be a statistically significant predictor for local recurrence, we believe that these patients should receive a more intense follow up than those with a negative margin. Though we agree ISM

does note describe a unique biological process and this group of patients in reality has a mixture of positive and negative surgical margins, we believe the chance of developing a recurrence as after a PSM in reality is bigger than having a negative margin.

Further studies on uncertain surgical margins are certainly required before any strong recommendations can be made. This study stands out as the only one, to our knowledge, focusing on ISMs. However, it is limited by its retrospective design and relatively small cohort of 24 ISM cases. The study is also missing some important variables such as nephrometry scores that could evaluate complexity of the tumours operated on in our cohort.

Additionally, since only malignant histology reports are found in the cancer registry, we lack information on recurrence without histological confirmation or whether redo operations with negative histology were performed. Thus, it is likely that local recurrence and particularly distant metastasis are underestimated. We consider histologically proven recurrence to have clinical significance for the patients' prognosis and data from the Norwegian cancer register are of high quality and provide great opportunities for real-world assessment of cancer related outcomes.

6. Conclusion

Our study shows that ISMs is an uncommon finding following PNs. Low surgical volume, treatment at non-university hospitals, Fuhrmann grade 1 and the use of more than 10 histological sections, were risk factors for ISMs. We found that patients with ISMs had a higher risk for local recurrence and should be followed more closely than those with negative margins. This risk was however smaller than those with PSMs.

Acknowledgements

The study was approved by our Institutional Review Board and by Regional Committees for Medical Research Ethics in Norway. In accordance with national regulations, our study did not require informed consent from patients for data extraction from the Cancer Registry of Norway, as the inclusion in the register is mandatory.

Conflicts of Interest

The authors do not have any conflicts of interest to report.

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