# **Original Article**

# Complications following biopsy of an intraabdominal or retroperitoneal mass compared with a renal mass

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#### ABSTRACT

**INTRODUCTION.** This study aimed to assess the short-term complication rate after US-guided core needle biopsies with an 18gauge needle of retroperitoneal or intraabdominal masses (non-kidney group) compared with complications after biopsy from a renal mass (kidney group).

**METHODS.** This was a retrospective analysis of 330 consecutive patients in the non-kidney group and 330 control patients in the kidney group. We recorded baseline characteristics, diagnostic yield, complications graded as Clavien-Dindo (CD) and readmissions within one and seven days.

**RESULTS.** In all, 245 patients in the non-kidney and 281 patients in the kidney group had a biopsy performed. A total of 54 (22%) patients in the non-kidney group had a complication registered. However, 47 were minor complications (minor bleeding or localised pain, CD 1). In the kidney group, 47 (17%) patients had a complication, with 44 being graded as CD 1. No major complications (CD 3 or higher) were associated with the biopsies. Only 0.8% of patients in the non-kidney group and 0.7% in the kidney group had a treatment-requiring CD 2 complication (i.e. blood transfusion) directly caused by the US-guided biopsy. These complications were recognised less than 30 minutes or more than four hours after the procedure. We found no significant difference in the complication rate, diagnostic yield or risk of re-admission between the two groups.

**CONCLUSION.** The observation period for patients who undergo an uncomplicated US-guided biopsy from an intraabdominal or retroperitoneal mass can safely be reduced to 30 minutes.

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Percutaneous core needle biopsies (CNB) are used in diagnostic work-up of suspected malignancies. Compared with CT-guided procedures [1, 2], ultrasound (US)-guided CNB have the benefits of lower cost, no ionising radiation and real-time imaging, allowing the radiologist to monitor the motion induced by respiration, thus compensating for the movements of internal organs [1, 2].

In recent years, the indication for CNB has increased to reduce unnecessary surgery for benign conditions, especially owing to improved diagnostic accuracy [3]. Previous work has shown that the post-procedural observation period following CNB of kidney masses can safely be reduced from four hours to 30 minutes [4, 5]. This practice was implemented at our institution in 2018.

In contrast, after CNB of other retroperitoneal or intraabdominal masses, the observation period remains four hours.

This study aimed to compare complication rates and readmission rates in patients undergoing a CNB from either non-kidney tissue or a kidney mass. We hypothesised that the observational period could also safely be reduced to 30 minutes for patients undergoing a CNB from a retroperitoneal or intraabdominal non-kidney mass.

#### Methods

#### Study populations

We identified 330 consecutive patients planned for a US-guided CNB from an intraabdominal or retroperitoneal non-kidney mass from 1 July 2018 to 13 July 2022 at the Department of Urology, Herlev and Gentofte Hospital, Denmark. A control group was formed by choosing the next patient scheduled for US-guided CNB of a kidney mass, producing 330 control patients from the same period. The procedures were mainly performed by three dedicated radiologists specialised in US-guided procedures who used a fully automatic biopsy gun under local anaesthesia, using an 18-gauge core needle in both groups.

Pre-biopsy workup included ensuring that anticoagulant medicine was paused according to national guidelines and that patients with an increased risk of bleeding had an international normalised ratio (INR) below 1.5 and a thrombocyte count above 40  $\mu$ l. Patients who did not meet these criteria were rescheduled. Patients were not included in this study until they were ready to undergo a biopsy.

Post-biopsy observation included regular measurements of pulse and blood pressure. Patients were discharged in case of an uncomplicated CNB and an uneventful observation period with stable vitals. However, if the radiologist reported a complicated procedure or an elevated risk of complications, the patient stayed for further observation. A nurse noted in the patient chart if there had been any problems, i.e. pain or bleeding. A doctor was summoned to assess the patient in case of major complications or doubts.

A retrospective electronic patient chart review was performed with registration of pre-biopsy baseline data, postbiopsy complications and readmission. Pre-biopsy baseline data included gender, age, use of anticoagulant medicine, INR and thrombocyte count, tumour size and location, number of core biopsies taken and diagnostic yield determined as diagnostic (benign or malignant) or non-diagnostic. Post-biopsy complications and readmission within one and seven days were registered, and complications were graded according to the Clavien-Dindo (CD) Classification, Supplementary Table 1 [6]. A complication graded as  $CD \ge 3$  was considered a major complication.

The estimated cost savings in Danish kroner (DKK) owing to reduced observation were calculated for liver biopsies.

The local institutional review board approved this retrospective study (WorkZone id 20056395).

#### Statistical analysis

The groups were compared by logistic regression, the Kruskall-Wallis test and the  $\chi^2$  test. Statistical analyses were performed with Microsoft Excel (2019) and R version 4.0.0. (R Foundation for Statistical Computing). A p-value < 0.05 was considered statistically significant.

Trial registration: not relevant.

Results

We identified 330 patients scheduled for US-guided CNB from an intraabdominal or retroperitoneal non-kidney mass, among whom 85 did not undergo the procedure (**Figure 1**). Thus, 245 patients in the non-kidney group had a CNB performed. Similarly, among the 330 patients scheduled for a US-guided CNB from a kidney mass, 49 patients did not undergo the procedure (Figure 1). Thus, 281 patients in the kidney group had a CNB performed. The target organs for the non-kidney CNB were liver (142 cases), retroperitoneal lymph node (91 cases), abdominal lymph node (41 cases), adrenal gland (18 cases) and other tissues (38 cases).

### FIGURE 1 Flow diagram of reasons for biopsies in the two groups not being performed.

## Non-kidney Kidney Admitted for biopsy: 330 Admitted for biopsy: 330 No biopsy: 85 No biopsy: 49 Malignancy was ruled out: 45<sup>a</sup> Malignancy was ruled out: 31<sup>a</sup> Not technically possible: 25 Not technically possible: 13 Tumour not accessible: 7 Tumour not accessible: 0 Risk of bleeding: 2<sup>b</sup> Risk of bleeding: 0 Others: 6° Others: 5° Biopsied: 245 **Biopsied: 281**

a) Mainly due to findings of haemangioma or benign cysts in the liver along with angiomyolipoma or benign cyst in the kidney.

b) Both cases involved a lymph node surrounded by large blood vessels. During the ultrasound, the radiologist assessed that the biopsy entailed a very high risk of perforating the blood vessels.c) In five cases, the tumour could not be recognised by ultrasound. In one case, the tumour was deemed too small for biopsy. Two patients did not want the biopsy after ultrasound. Two cases of suspected infection at the target organ were recorded. In one case, the biopsy was terminated due to a lack of cooperation from the patient, the biopsy was later done in general anaesthesia.

#### **Baseline characteristics**

Baseline characteristics are presented in **Table 1**. Compared with patients in the kidney group, patients in the non-kidney group were slightly older, a larger proportion were men and more were treated with anticoagulant medicine. All patients on anticoagulant medicine had paused this medication according to national guidelines. The tumour sizes were comparable in the two groups, whereas more patients in the kidney group had more cores taken during the procedure.

**TABLE 1** Baseline characteristics of patients who underwent an intraabdominal or retroperitoneal ultrasound-guided core needle biopsy stratified by target organ.

	Non-kidneyª (Nn = 245)	Kidney (Nk = 281)	p value
Age, median (IQR), yrs	73 (67-78)	70 (60-76)	< 0.001 <sup>b</sup>
Sex, n			< 0.001°
Female	60	108	
Male	185	173	
Anticoagulation?, n			0.045°
Yes	91	81	
No	154	200	
Tumour size, median (IQR), cm	2.5 (1.6-3.8)	2.7 (1.8-4.0)	0.07 <sup>b</sup>
Patients with biopsy cores, n			< 0.001°
1	72	25	
2	134	147	
≥ 3	39	109	

IQR = interquartile range.

a) Liver (92 cases), retroperitoneal lymph node (77 cases), abdominal lymph node (30 cases), adrenal gland (13 cases), other tissues (33 cases).

b) Kruskall-Wallis test.

c) χ² test.

#### Diagnostic yield

No difference was recorded in diagnostic yield in the two groups. The pathologist assessed the obtained histology to be diagnostic in 228 out of 245 (93.1%) non-kidney CNB and 261 out of 281 (92.9%) kidney CNB,  $\chi^2$  test p = 0.57.

#### Complications

In total, 54 (22%) patients in the non-kidney group had a complication: 47 were graded as CD grade 1, five CD grade 2 and two CD grade 3a. In comparison, 47 (17%) patients in the kidney group had complications: 44 CD grade 1 and three CD grade 2. No correlation was recorded between the number of cores and complication rates (**Table 2**). Patients in the non-kidney group had a non-significantly higher risk of having a complication (odds ratio (OR) = 1.41; 95% confidence interval (CI): 0.91-2.18) or a CD grade 2-3a complication (OR = 2.73; 95% CI: 0.70-10.66).

	Non-kidney (N <sub>n</sub> = 245)			Kidney (N <sub>k</sub> = 281)		
Biopsy cores	no complication	any complication	CD 2-3a	no complication	any complication	CD 2-3a
1	57	15	3	21	4	1
2	106	28	4	121	26	1
≥ 3	28	11	0	92	17	1
	1					

#### TABLE 2 Correlation between number of biopsy cores and complications. Values are n.

CD = Clavien-Dindo classification.

The most frequently observed CD 1 complication was pain at the biopsy site, either mild with no need for treatment or moderately treated with oral analgesics (29 in the non-kidney group and 30 in the kidney group), followed by minor bleeding from the puncture site or localised suggillations (16 in the non-kidney group and 19 in the kidney group).

Table 3 presents the patients with CD 2 or 3a complications. Most complications recorded in patients undergoing a CNB from a non-kidney mass were caused by additional work-ups performed close to the time of the CNB. Only two (0.8%) patients in the non-kidney group had a CD 2 complication that was directly caused by the CNB (one was a case of bleeding after biopsy from the spleen requiring blood transfusion; the other, a case of fever after biopsy from a retroperitoneal lymph node). Similarly, two (0.7%) patients in the kidney group had a CD 2 complication caused by the CNB (one was a case of retroperitoneal bleeding, requiring blood transfusion; the other, a case of other, a case of macroscopic haematuria, requiring an irrigation catheter).

#### TABLE 3 Analysis of the Clavien-Dindo grade 2 and 3a complications.

Patient	Anticoagulation	Location of biopsy	Complication and treatment	Time until recognising the complication	Comments		
Assessed to be caused by the biopsy procedure							
60-yr-old female	Clopidogrel <sup>a</sup>	Kidney	Bleeding, blood transfusion, CD 2	< 30 min.			
72-yr-old female	None	Kidney	Macroscopic haematuria, irrigation catheter, CD 2	< 30 min.	•		
67-yr-old male	Clopidogrel <sup>a</sup>	Retroperitoneal lymph node	Fever, antibiotics, CD 2	7 hrs	Treatment not initiated until the next day		
81-yr-old male	Clopidogrel <sup>a</sup>	Spleen	Bleeding, blood transfusion, CD 2	During the biopsy	-		
Assessed to be unre	elated to the biopsies <sup>b</sup>						
66-yr-old female	None	Kidney	Local infection in the neck, CD 2	3 days	Biopsy of a lymph node in the neck during the same US procedure		
83-yr-old male	None	Tumour in front of the bladder	STEMI, PCI, CD 3a	6 days	-		
81-yr-old male	Rivaroxabanª	Retroperitoneal lymph node	Macroscopic haematuria and urinary infection causing endocarditis, antibiotics, CD 3a	4 days	Ureteroscopy the day before the biopsy		
47-yr-old male	None	Retroperitoneal lymph node	Infection, antibiotic, CD 2	36 hrs	Infection prior to the biopsy Bilateral nephrostomies were performed in the same session as the biopsy		
81-yr-old male	Dabigatranetexilate <sup>a</sup>	Retroperitoneal lymph node	Macroscopic haematuria and urinary retention, catheter, CD 2	5 days	Recently diagnosed with bladder cancer, had TUR-B		
73-yr-old male	None	Retropertioneal lymph node	TCI, no treatment, CD 2	6 days	2 wks earlier		
					Started chemotherapy 3 days prior		

CD = Clavien-Dindo classification; PCI = percutaneous coronary intervention; STEMI = ST-elevation myocardial infarction; TCI = transient cerebral ischaemia; TUR-B = transurethral resection of bladder; US = ultrasound.

a) Paused according to national guideline.

b) A consequence of other intervention/work-up during the same period as the biopsies.

The only two major complications (CD 3a) observed were deemed very unlikely to be a direct result of the biopsy: One patient had a urinary infection resulting in endocarditis. However, a retrograde ureteroscopy was performed the day before the CNB of a retroperitoneal lymph node and was deemed to have caused the infection. The other patient experienced a myocardial infarct six days after an otherwise uncomplicated biopsy.

Both recovered without further complications.

Three of the four genuine complications in need of treatment (CD 2) were recognised before 30 minutes; all three were due to bleeding, as described above, Table 3. The last patient, recognised after seven hours, remained stable, and antibiotic treatment was postponed until the following day. The unrelated CD 2 and 3a complications were recognised 1-6 days after the CNB (Table 3).

#### **Re-admissions**

One patient in the non-kidney group was readmitted during the first day, whereas in the non-kidney group, ten patients were readmitted 2-7 days after their CNB. The corresponding numbers for patients in the kidney group were two patients during the first day and six patients during days 2-7. Again, no significantly increased risk was recorded of readmission for patients in the non-kidney group compared with patients in the kidney group (one day: OR = 0.52; 95% CI: 0.05-6.34; seven days: OR = 2.48; 95% CI: 0.83-7.35).

#### Cost savings

The cost of a liver biopsy (DKK 3,164), blood test (DKK 59) and four hours of observation (DKK 384), a total of DKK 3,607, would be reduced by 9% if the observation had been reduced to 30 minutes (DKK 48), a total of DKK 3,271.

#### Discussion

We found a higher overall complication rate following US-guided CNB of intraabdominal and retroperitoneal masses than previous studies, but this was mainly due to minor complications (CD 1). This study included any report of non-serious pain or localised bleeding as a CD 1. Other authors may have deemed these findings expected after CNB, explaining the very low reported complication rates of these studies (less than 5%) [1, 3-5, 7-9]. Although the overall complication rate was 22% in the non-kidney group and 17% in the kidney group, the proportion of treatment-requiring complications (CD 2) directly caused by the biopsies was less than one percent in both groups. We found no significantly increased risk of complications or readmission among patients who underwent CNB from a non-kidney mass compared with patients undergoing CNB from a kidney mass. Additionally, no correlation was observed between the number of cores obtained during the CNB and the rate of complications. Finally, all CD2-3a complications (both associated with the biopsies and caused by other workups) were either recognised early (within 30 minutes of observation) or did not occur within the first four hours following the procedure.

Our findings are in accordance with previous studies reporting a low risk of major complications following USguided CNB of a kidney mass (range: 1-2%) [3-5] and other intra-abdominal and retroperitoneal masses [1, 7-9]. Moreover, adding two or more cores of renal mass did not elevate the risk of a complication compared with one core [10-12].

The present study included only one CNB from the spleen. The splenic procedure was complicated by bleeding, which was recognised during the procedure, Table 3. Previous work has shown that a CNB with an 18-gauge needle from the spleen is safe with a low risk of complications [11]. This was confirmed in a meta-analysis of 859 spleen biopsy procedures including 370 CNB. The risk of a post-biopsy complication following use of an 18-gauge or smaller needle was 3.6%, of which 1.9% were major complications. Use of a larger needle increased the risk of major complications to 12.5% [12]. In our institution, the standard needle size is 18-gauge.

Previous studies have demonstrated that one hour of observation after an 18-gauge CNB of the liver is safe and cost-effective [8, 9]. Both studies showed no increase in adverse outcomes in the group with early discharge

compared with the standard observation period of at least four hours. In contrast, the studies reported a significantly reduced cost associated with a one-hour observation period. Another study found that US-guided CNB of suspected malignancies reduced the total number of tests and the length of hospital stays, reducing the cost by approximately 20% [13]. Our study supports that a short observation is safe after US-guided CNB of the liver and associated with a 9% cost reduction.

Altered coagulation, particularly an INR over 1.5, increases the risk of bleeding following CNB and is considered a relative contraindication [14]. In contrast to the low risk of bleeding after CNB of a kidney mass, patients with a parenchymal kidney biopsy due to a medical kidney disease had an increased risk, especially of bleeding, with haematomas in up to 11% of the cases [15]. Both patients who required a blood transfusion following CNB (Table 3) received anticoagulated treatment, resulting in an overall 1% blood transfusion incidence (2/172) in patients on anticoagulated treatment compared with 0% (0/353) in patients not on anticoagulated treatment. The present study was not designed to investigate factors associated with an increased risk of complications, and the two events do not allow for any meaningful statistical comparisons. However, all patients in anticoagulant treatment had paused the medication according to national guidelines, and the measured INR and platelet counts were in the recommended range. It may be speculated that patients on anticoagulated treatment have an increased risk of post-biopsy bleeding even with a low INR, normal platelet count and paused anticoagulant treatment. However, our data do not warrant any change in the current guidelines, and this supposition needs to be investigated in a study designed to answer this question.

#### Limitations

The main limitation of this study was its retrospective design and thereby potential underestimation of complications. Some patients may have had complications managed by their general practitioner. Such complications would not have been recorded in our study. However, the standard practice for general practitioners in our region is to refer patients with serious complications to the department where the procedure was performed. In addition, electronic patient chart review enabled access to complications treated at any hospital in Eastern Denmark. Thus, it seems unlikely that any serious complications occurring within seven days were missed.

We focused on early discharge safety and complications within the first seven days following a US-guided CNB. Potentially, later complications may have been missed, but such complications would probably not be relevant for the safety of early discharge.

To increase the robustness of our findings, a larger sample size is needed.

#### Conclusion

Based on the findings of this study, the observation period for patients with an uncomplicated US-guided CNB from an intraabdominal or retroperitoneal non-kidney mass can safely be reduced to 30 minutes.

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