

Routine deferred computed tomography for patients with suspected urolithiasis is low-value healthcare.

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Running head: Routine CT for suspected urolithiasis

Abstract:

Objective: The aim of this study was to investigate the benefits of deferred routine computed tomography of the kidneys, ureters and bladder (CT KUB) for patients with a self-limiting episode of suspected urolithiasis. **Material and methods:** The study comprised a case series of consecutive patients examined with deferred routine CT KUB for control of suspected urolithiasis. Patients examined with CT KUB at the University Hospital of North Norway, between 1 January 2010 and 31 December 2013, were included. The final analysis included 189 CT KUBs (response rate 48%). All data were extracted from the patient case files. The primary endpoint was the proportion of asymptomatic patients with a confirmed diagnosis of urolithiasis on CT KUB that led to surgical intervention within 1 year from the initial CT scan. **Results:** At the time of CT KUB 171 (90%) patients were asymptomatic, of whom three (1.8%) were treated. Urolithiasis was confirmed on CT KUB in 23% of asymptomatic patients. **Conclusion:** Deferred CT KUB did not alter clinical outcome for the great majority of asymptomatic patients. The majority of patients that received adequate pain relief in primary care remained asymptomatic, and did not need specialized healthcare. To refrain from CT KUB involves little risk. Deferred CT KUB for patients with suspected urolithiasis is a low-value healthcare service.

Key words: urolithiasis; guidelines; computed tomography; low-value healthcare;

Introduction:

Calculi in the urinary tract are common: in the USA one person in 11 will have a kidney stone during their lifetime [1]. It is unknown whether the observed increase in urolithiasis [1-3] is due to a real increase in incidence, an increased use and sensitivity of imaging modalities [4] and/or lower threshold for contacting the healthcare system. The charges for emergency department visits for urolithiasis increased by 10% annually between 2006 and 2009, and amounted to 5 billion USD in 2009 [2]. Emergency department visits due to flank or kidney pain increased significantly from 1996 to 2007, together with a more than tenfold increase in the use of CT KUB. The proportion that was diagnosed with urolithiasis was not increased [5].

There is consensus in the urology community that patients presenting with suspected urolithiasis should have their tentative diagnosis supported by appropriate imaging. The European Association of Urology (EAU), The American Urological Association (AUA), and American College of Radiology recommend CT KUB because of the high sensitivity and specificity compared to other imaging modalities [6-8]. The high expenses and radiation exposure associated with CT KUB cause for concern [2, 5, 6, 8]. In the EUAs 2015 guideline ultrasound is now described as the preferred initial imaging modality. Still the recommendation on CT KUB remains: "Following initial ultrasound assessment, non contrast computerized tomography should be used to confirm a stone diagnosis in patients presenting with acute flank pain, because it is superior to intravenous urography" [6].

The guidelines do not specify when to suspect urolithiasis, when to refer a patient for CT KUB and when not to. The EUA states: "Patients with ureteral stones usually present with loin pain, vomiting, and sometimes fever, but may also be asymptomatic" [6]. When to suspect urolithiasis is therefore largely left to the individual physician's clinical discretion. The guidelines do not describe management of suspected urolithiasis in primary care.

Most ureteral stones pass spontaneously [7, 9, 10]. Only 1.1% of asymptomatic stones need intervention [11]. In Norway, patients with ongoing severe symptoms of suspected urolithiasis are commonly hospitalized acutely. However, in cases where the pain resolves either spontaneously or conservatively they are discharged from the emergency room or leave their general practitioner (GP) with a referral to CT KUB within 2-6 weeks [12]. The practice is not based on evidence of patient outcomes. The argument is that most ureteral stones pass spontaneously within 40 days [3, 9], and a deferred CT KUB can both control passage and be diagnostic for stones remaining after the expected time of passage.

Objective:

We aimed to investigate the clinical benefits for patients managed with deferred routine CT KUB after a self-limiting initial episode of suspected urolithiasis.

Materials and methods:**Study design:**

This study is a case-series of consecutive patients investigated with deferred CT KUB. We determined the probability of a positive finding of urolithiasis and the extent of interventions performed on both symptomatic and asymptomatic patients.

Setting:

The University Hospital of Northern Norway (UNN) is a state owned hospital with locations in Tromsø, Harstad and Narvik. UNN is the local hospital for 200,000 inhabitants. In the attachment area there are no other CT scan providers. The GP refers the patients to specialized health services including imaging investigation, when needed.

Participants:

From a search of patient case files at UNN from 1 January 2010 to 31 December 2013, patients with suspected urolithiasis and deferred CT KUB were identified and included on the basis of the referral information. All patients referred to CT KUB with a suspicion of urolithiasis were included, regardless of how the symptoms were described. Patients with a CT-verified calculus within 1 year before the CT where the calculus was not removed, patients under 18 years of age, pregnant patients and patients with persistent symptoms for more than 3 weeks at the time of referral were excluded from the study.

The inclusion criteria were fulfilled in 438 patients of whom 28 were not invited, 10 because they had died and 18 because we could not get a contact address. Patients were contacted by letter with information of the study and a consent form. Among 410 invited patients, 197 (48%) accepted to participate and gave us permission to study their hospital records (fig. I). Fourteen cases were excluded from the analysis because further investigation of their hospital record showed that five patients had symptoms for more than three weeks at the time of referral, four patients had a stone diagnosis within 1 year prior to the CT and five patients had been converted to immediate imaging due to worsening of clinical symptoms. Six participants had two independent episodes of suspected urolithiasis and were referred to deferred CT KUB twice in the period of investigation yielding 203 CT KUBs. Final analysis included 189 CT KUBs.

Data collection:

All data was extracted from the patient case files. CT findings, age, gender, previously known urolithiasis, time from symptom onset to referral, time from referral to CT imaging, clinical symptoms after referral, additional imaging diagnostics, urologic appointments, and treatment within one year from the initial CT were registered.

Ethics:

The Regional Committee for Medical and Health Research Ethics approved the study. Written consent was obtained from all participants.

Outcome Measurements and Statistical Analysis:

The primary endpoint was the proportion of asymptomatic patients with a confirmed diagnosis of urolithiasis on CT KUB that led to surgical intervention within one year from the initial CT scan. Patients with absence of pain or discomfort by the time of CT KUB were classified as asymptomatic. For patients without any clinical follow-up visit at the hospital, the authors had no knowledge about symptoms after the CT referral. These patients were classified as asymptomatic in the analysis, as they did not exhibit symptoms judged necessary of specialized healthcare. Surgical intervention was defined as any intervention performed to treat or alleviate urolithiasis, including extracorporeal shock wave lithotripsy, ureteroscopic lithotripsy, and ureteral stenting among others. At UNN, common indications for active stone removal are severe or persistent symptoms of urolithiasis combined with a confirmed radiological diagnosis. Interventions in asymptomatic patients were regarded as interventions induced by the CT KUB.

The secondary endpoints were the proportion of asymptomatic patients and the amount of intervention performed on symptomatic patients. Logistic regression analysis of the probability of both positive findings and intervention were performed with the following covariates: age, gender, haematuria, previously known urolithiasis, duration of symptoms at referral, and time from referral to CT.

Results:

Out of 189 CT KUBs, 79 (42%) were performed on women and 110 (58%) on men (table I). The mean age was 55 years. The majority was referred to CT KUB after maximum one day of symptoms. GPs had ordered 95% of the referrals. By the time of CT KUB 90% were asymptomatic of whom 23% got a confirmed diagnosis of urolithiasis (table II). Three asymptomatic patients underwent surgical intervention.

Of asymptomatic patients with a confirmed diagnosis of urolithiasis 25 had kidney stones, 11 ureteral stones, and 4 bladder stones (table III). The majority had one stone while 10 patients had two to nine stones, all located in the kidneys. Median size for all calculi was 4 mm (range 1-17). Median size for kidney and ureteral stones were 3 mm (1-14) and 4 mm (3-7), respectively. Hydronephrosis was present in two asymptomatic patients, of whom one received intervention and one passed a 3 mm ureteral stone spontaneously. The subsequent follow-up CT showed no sign of hydronephrosis. In 168 patients, there was no information on urolithiasis in the case record after referral, including 37 patients with positive CT. Of these patients, 24 had kidney stones, nine ureteral stones, and four bladder stones, median stone size was 3.5 mm.

In logistic regression analysis, only gender was significant in the probability of positive findings, with an odds ratio of 2.50 for men ($p = 0.025$, 95% confidence interval 1.12 – 5.58). None of the variables were significant predictors for intervention.

The characteristics of asymptomatic patients who received intervention are shown in table IV. Three male patients were classified as asymptomatic, and got treatment, two with ureteral stones and one with a kidney stone. Out of 18 symptomatic patients, 12 underwent surgical intervention and six passed a stone spontaneously. The characteristics of symptomatic patients that received intervention are shown in table V. All symptomatic patients that were treated had symptoms for a minimum of seven weeks before intervention. Four symptomatic patients had hydronephrosis, all were treated.

Follow-up for conditions other than urolithiasis revealed on CT KUB was offered to 20 patients (11%). Four patients received treatment, one each for small intestine adenocarcinoma, bladder cancer, ureterocele, and gallstones. The carcinoid tumour was an incidental finding, while the three other patients presented symptoms that induced intervention. CT findings of possible calculi or incidental findings of possible malignant processes resulted in both imaging and physician consultation for 16 patients. All 16 cases were concluded with benign conditions with no need of treatment.

Discussion:

This study found close to no benefit of CT KUB for patients remaining asymptomatic after a self-limiting episode of suspected urolithiasis. The great majority of patients with suspected urolithiasis that do not need immediate specialized care, do not need specialized care at all. In this population 90 % of patients remained asymptomatic and without specialized healthcare follow-up.

These data suggest that routine CT KUB for all patients with suspected urolithiasis represents a low-value healthcare service. The risk associated with refraining from CT KUB for asymptomatic patients is marginal. Only one examined patient had an asymptomatic calculus that caused persistent hydronephrosis, which untreated could represent a risk for kidney damage. There is international attention to reduce the use of medical interventions that provide no or marginal benefit [13, 14]. Overuse of CT is of public concern [15] and we argue that managing self-limiting episodes of urolithiasis with routine CT KUB is overdiagnosis, and accordingly should be avoided.

Surgical treatment was offered to three patients with registered symptoms for less than 1 month. For the 62-year-old patient with ureteral calculi and hydronephrosis, active stone

removal was induced by the CT KUB. For the other ureteral patient, the case record is insufficient in regard of symptoms. The available sources gave no information on his symptoms and one can only speculate on whether symptoms or the CT image itself caused the intervention. The final treated asymptomatic patient had a kidney stone without hydronephrosis, which had been asymptomatic for six months. It is questionable if this intervention was necessary as there is no advantage of prophylactic treatment of asymptomatic calyceal stones [6].

The present findings also indicate that the practice of deferred imaging is safe, as Lindqvist et al. have demonstrated [16]. The majority that got a confirmed diagnosis of urolithiasis had calculi smaller than 5 mm in renal calices, calculi that most often are asymptomatic [6]. Two asymptomatic patients got a confirmed diagnosis of kidney stones that were 6 mm or smaller on their CT KUB while their ureter was slightly dilated. The calculi causing the symptoms of urolithiasis had most probably already passed at the time of CT KUB. Knowing this, it is reasonable to believe that the symptoms of a proportion of patients had no connection to the finding on CT KUB, and thus the benefit of the confirmed diagnosis questionable. It is impossible to assess if whether the total 69% with negative CT KUBs had passed a calculus already or were suffering symptoms of other conditions than urolithiasis.

Hydronephrosis was present in 22% of symptomatic patients. The symptomatic patients in our analyses constitute a subgroup easily identified by the persistence of their symptoms, everyone had symptoms for more than 7 weeks before intervention. Our results show that patients with persistent symptoms should have imaging examination both for treatment planning and for the assessment of possible hydronephrosis.

GPs had ordered almost every CT, which demonstrates that the decision of deferred CT is made in primary care. This corresponds well with the clinical distinction between patients with urgent need of hospitalization for severe symptoms of urolithiasis and patients with a shorter self-limiting episode. The results indicate that almost every patient admitted to our hospital acutely get their CT KUB during the admission.

The extensive cost and considerable radiation exposure of CT KUB for managing urolithiasis are well documented [2, 8, 17]. In a multicentre study Smith-Bindman et al. compared patient outcomes when initial investigation was ultrasound or CT KUB respectively, and found no significant differences in complication rates, pain scores, emergency department visits or hospitalization rates. The CT KUB group had a significantly higher radiation exposure [17]. Many recommend ultrasound as the primary imaging modality [6, 17-19]. Ultrasound screening for asymptomatic patients would in our population have detected potential damaging conditions due to urolithiasis with equal sensitivity as CT KUB. The sensitivity of ultrasound detecting hydronephrosis is close to 100 % [20]. Therefore, we support the recommendation of ultrasound as the primary modality if imaging diagnostics are chosen for asymptomatic patients.

However, implementation of low-dose CT KUB can limit the radiation exposure down to 0.6 mSv[21], and would make the radiation argument of avoiding CT less relevant. Falling outside of the scope of our study, further research should assess the costs of deferred ultrasound diagnostics compared to low-dose CT KUB. Also the cost and clinical implication of incidental findings of the two modalities should be assessed.

As reported by others, the positive rate for urolithiasis was lower for women than men, [18, 19] and could not be explained by other covariates. No asymptomatic woman was treated

for urolithiasis. Special caution towards the use of CT KUB in women has been advocated [18, 19]. Our results support this recommendation.

Apart for one incidental finding of a gastrointestinal tumour, patients treated for other conditions than urolithiasis had persistent symptoms. These patients would probably have been recognised and treated without routine CT KUB after a self-limiting episode of suspected urolithiasis. In this group, there were more patients receiving unnecessary follow-ups for findings that turned out to be benign, than patients being treated for urolithiasis. The economical burden of incidental findings is substantial while the medical benefit is questionable [22]. The one incidental finding of clinical importance is not an argument for routine CT KUB.

The strength of our study is the fact that UNN is the only provider of specialized care and CT diagnostics in the area, creating a representative patient population. The participation rate was only 48%, however such a rate is not uncommon when postal written consent has to be obtained several years after the relevant episode. The degree to which this sample is representative for all patients examined with CT KUB is therefore hard to assess. It is nevertheless reasonable to believe that patients more afflicted with urolithiasis are more motivated than others to participate in a urolithiasis study. It is therefore not likely that the low benefit conclusion is threatened by a low participation rate.

The information in some of the referral letters was insufficient. For some of the patients, the duration of symptoms at referral, status for haematuria and previously known urolithiasis, and/or symptoms after referral were not known. Furthermore, the descriptions of pain were sometimes imprecise. Our study cannot answer how primary care physicians dealt with the CT findings. Further studies are warranted to assess if more information on duration and characteristics of symptoms better can identify potential subgroups with increased or

diminished risk associated with refraining from imaging diagnostics. Separate gender and age analysis should be performed.

In conclusion, the practise of imaging diagnostics for all patients with suspected urolithiasis is not evidence based. In this study the great majority of patients with suspected urolithiasis that received adequate pain relief in primary care remained asymptomatic, and did not need specialized healthcare. Deferred CT KUB did not alter clinical outcome for the great majority of asymptomatic patients. Refraining from CT KUB involves little risk. Deferred CT KUB for patients with suspected urolithiasis is a low-value healthcare service. The authors recommend that its routine use should be avoided and replaced by a process of shared decision making. Asymptomatic patients should receive information on benefits and risks of imaging examination, in addition to thorough information on when to seek help again. If experiencing persistent symptoms, CT KUB should be recommended.

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Declaration of interest:

The authors have nothing to disclose.

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