Title

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Title: Prevalence of Incidental Findings on Abdominal CT Angiograms on Prospective Renal Donors

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Abbreviations:

AASLD: American Association for the Study of Liver Disease

ACR: American College of Radiology

CT: computed tomography

IF: incidental findings

MDCTA: multi-detector CT angiogram

NASH: Non alcoholic steatohepatitis

CTU: CT Urogram

Abstract

Objective: To evaluate the prevalence of incidental findings on pre-operative Abdominal CTA/CTU in asymptomatic prospective renal donors.

Methods:

A HIPAA-compliant, IRB-approved retrospective study of 1597 subjects undergoing renal transplant evaluation from June 1, 2006 to March 31, 2011 was performed. Candidates underwent multi-phasic MDCTA/CTU for pre-surgical evaluation of renal vascular and parenchymal anatomy. All scans were reviewed by one of three fellowship trained abdominal radiologist. The diagnoses were made on the basis of CT characteristics of each lesion and pathology confirmation was available for seven patients. We calculated the prevalence of each incidental finding, performed Fisher exact test or X^2 test for categorical variables between the cohort that did and did not undergo donor nephrectomy and performed simple linear logistic regression analysis of incidental findings which predicted renal donation.

Results:

Of the 1597 potential donors, 58.4% were female and the mean age was 42.6 years (range 18-74). 1,195 (74.9%) had a total of 2105 incidental findings. Based on American College of Radiology Incidental Findings Committee White Paper on Managing Incidental Findings on Abdominal CT, 17.3% had incidentalomas and 1.1% required follow up. Majority of the incidental findings (16/17) were in patients who did not undergo renal donation. The prevalence of pathologically-proven malignancy was 0.1% (3/1597).

Conclusion:

Pre-operative CTA/CTU not only identifies vascular anatomy but may help detect clinically significant unanticipated findings in otherwise healthy population.

INTRODUCTION:

Multi-detector CT Angiography and Urography (MDCTA/CTU) has replaced conventional angiography for assessment of renal vascular anatomy prior to living donor nephrectomy[1,2]. These studies may image the lung bases, abdomen and pelvis and thus have the potential to detect a wide variety of clinically occult abnormalities which may affect kidney donation. Characterization of these lesions is dependent on many factors including quality of the study and expertise of the radiologist. The characterized lesions are stratified by importance and significance to determine if they require no further workup or if they may potentially affect donor health requiring additional testing or sub-specialty referral.

The prevalence of incidental findings has previously been reported in studies evaluating CT colonography performed in older patients with high colon cancer risk.[3-7] However, the results of these studies may not be applicable to the younger and healthier potential donor nephrectomy population. Further, many findings cannot be adequately characterized on unenhanced CT, leading to further testing. To our knowledge, there have been no reported large cohort studies reporting the overall prevalence of significant non-vascular and vascular incidental findings on contrast enhanced CT scans performed in an asymptomatic prospective donor population.

Our transplant center is one of the largest in the United States and performs over 100 living donor renal transplants per year. Potential healthy donors undergo rigorous medical and psychosocial screening prior to donation. All of our donor candidates are evaluated by a transplant coordinator registered nurse, nephrologist, social worker, and psychiatrist. The donor team, including an independent donor advocate, advises the

candidate of the risks and benefits of further evaluation and kidney donation. The candidate is advised of the options of kidney donation by a multidisciplinary team including the donor and recipient surgeons after the anatomical results and incidental findings have been evaluated. If deemed a reasonable candidate for donation, each candidate will undergo abdominal MDCTA/CTU to evaluate the potential donor's kidneys and vascular anatomy to determine the most suitable side for nephrectomy. The primary purpose of this study was to determine the prevalence of incidental findings on preoperative MDCTA/CTU in a healthy cohort of potential renal donors on donor nephrectomy. An incidental finding, also known as an incidentaloma, may be defined as "an incidentally discovered mass or lesion, detected by CT, MRI, or other imaging modality performed for an unrelated reason"[8].

RESULTS

Of the 1597 potential donors, 665 (41.6%) were men and the mean age of the entire cohort was 42.6 years (range 18-74). 1,195 (74.9%) had a total of 2105 incidental findings detected on MDCTA/CTU (Figure 1). Of 1597 potential donors, there were 702 (44.0%) who underwent kidney donation and comprised the donor sub cohort. The remainder (895 (56%)) did not donate and comprised the non-donor subcohort.

Incidental findings

Incidental findings were seen in 1195 (74.9%) of patients. 73 (4.5%) had incidental findings of moderate or high concern, which warranted additional work up (Figure 1). Incidental findings were further stratified according to the American College of Radiology (ACR) Incidental Findings Committee White Paper on Managing Incidental Findings on Abdominal CT[8] (Table 1). Although the prevalence of each incidental finding alone did not differ between the two sub-cohorts, the prevalence of incidental findings requiring further work-up were significantly different between the donor and non donor sub-cohorts (0.1% vs 1.8%, $p<0.0001$) (Table 1).

Vascular incidental findings and findings not included in ACR White Paper considered moderate or high clinical importance were also tabulated (Table 2). 464 (29.0%) had additional non-solid organ / vascular incidental findings and 56 (3.5%) warranted additional follow-up. Hepatic steatosis was the most common incidental finding and was more prevalent in the group that did not undergo nephrectomy (14.9% v 6.7%, $p<0.01$). There was a significant difference in the proportion of incidental findings

requiring work-up between prospective donors who did and did not undergo nephrectomy.

Incidental findings which we would consider relative and absolute contraindication for donor nephrectomy are tabulated in Table 3.

Incidentally Detected Malignancies

There were three incidentally detected, pathologically-proven subclinical malignancies including a stage IV lung adenocarcinoma, grade 2 bladder cancer and gastrointestinal stromal tumor. The prevalence of malignancy was 0.1% (3/1597). Seven operations were performed for incidentally detected lesions (Table 4).

DISCUSSION

Pre-operative MDCT Angiography and Urography has replaced conventional angiography to identify arterial and venous anatomy prior to donor nephrectomy. However unlike unenhanced studies, multi-phasic CT technique enables characterization of incidentally detected findings. In our overall study cohort of 1597 patients, we were able to characterize 95.4% of findings as benign or low importance leaving only 4.5% of incidental findings as warranting additional work-up. This is much lower than the 11-15% rate of moderate and high importance incidental findings reported in studies of unenhanced screening CT colonography and 21% rate of similar lesions detected in symptomatic patients[9].

The prevalence of incidental findings and the impact of incidental findings on donor nephrectomy have not been well-described in a large cohort. In this study we found that a variety of incidentally detected lesions of moderate to high importance were detected in the liver, kidney, pancreas, lung bases, and reproductive organs. The pathologically proven malignancy rate in the overall prospective renal donor population was 0.1%

Prior studies have criticized the workup required to characterize incidental lesion detected on unenhanced cross sectional studies. Detection of incidental findings create anxiety for patients and referring physicians and create a cycle of disclaimers and potentially unnecessary testing that further increase cost, anxiety and risk of procedure associated complications[10,11]. The American College of Radiology has recognized this problem and established guidelines for management of incidentalomas on Abdominal CT[8]. Similarly, the Committee for virtual colonography has codified and track

extracoloinic findings in the CT colonography classification system[12]. In our donor population, using the ACR Incidental Finding Classification of incidentalomas, a reasonable 1.1% of the cohort had incidental finding justifying follow-up studies. Our transplant radiologists directly communicate incidental findings during multidisciplinary transplant meetings and discuss the probability of disease with the team[13]. This interaction likely improves the team's level of concern and likely minimizes excessive work-up.

Subclinical hepatic steatosis was the most common incidental finding and was seen in 11.3% of potential donors. Population-based estimates of non-alcoholic fatty liver disease (NAFLD) have reported a prevalence of NAFLD ranging from 13-40% in the general population.[14,15] Patients with NAFLD have increased overall mortality compared to matched control populations[16,17]. Thus, the American Association for the Study of Liver Disease (AASLD) recommends screening for signs of metabolic syndrome and to exclude co-existing etiologies for chronic liver disease[18]. A minority of patients with NAFLD and risk factors for metabolic syndrome can have concomitant Non Alcoholic Steatohepatitis (NASH).[17] NASH as an indication for liver transplant has increased fivefold and is predicted to surpass alcoholic/ hepatitis-induced end-stage liver disease as the leading indication for liver transplant in the next several decades.[19]

Asymptomatic nephrolithiasis significantly impacted candidates proceeding to donor nephrectomy. At our center, we use the Amsterdam Forum On The Care Of The Live Kidney Donor guidelines to risk stratify patients with incidental nephrolithiasis.[20] An asymptomatic potential donor with history of single stone may be suitable for kidney donation if the patient does not have the following processes: hypercalcemia,

hyperuricemia, metabolic acidosis, cystinuria, hyperoxaluria, multiple stones or nephrocalcinosis. Once cleared of these conditions, they may be reevaluated for potential donation and if selected, the kidney with the stone burden is chosen for donation.

Existing international guidelines (i.e. Amsterdam forum guidelines) stratify patient's risk using known history of disease or currently active medical conditions. In contrast, we generated a list of solid organ incidental findings which we felt would contraindicate renal donation (Table 3). This table lists anatomical findings that may preclude renal donation and exemplifies the benefit of having the detailed anatomical evaluation that is now possible with CTA/CTU. This is not a complete list, however, since there are many other findings that might preclude donation. This list complements the existing guidelines by providing solid organ lesions and abnormalities not previously known. We acknowledge that anatomic evaluation using CTA/CTU may not be a universal practice; however, we feel that there are significant benefits to the recipients and we want to give patients every hope and opportunity to achieve a successful transplant since the organ supply is limited.

The decision to donate is based on multiple factors, one of which is imaging. Our center participates in the National Exchange Program and thus, many more patients are screen compared to the patients who undergo donor nephrectomy. We do not consider blood type or crossmatch results as contraindications to donation since there are now numerous options that may allow living donor transplantation despite these limitations. The most common reason why a donor does not proceed with donation is because s/he is highly sensitized and it would be difficult to suppress these antibodies or find a

suitable exchange donor despite a national effort.. In addition, for a minority of patients who come from out of town, patients undergo screening by nephrology, have laboratory studies done and imaging performed on the same day for convenience to the patients. This may explain why only a minority of our patients with imaging ultimately underwent donor nephrectomy.

In this study, there was a 0.2% malignancy rate in an asymptomatic adult population and two of three were identified at an early stage. A prior small cohort study evaluating CTA/CTU in 200 potential donors failed to detect any incidental malignancies likely due to cohort size[21]. In our population, one potential donor with a gastric lesion underwent surgical resection of a stage I gastrointestinal stromal tumor. A second potential donor had a transurethral resection of a stage I transitional bladder cancer. The third potential donor had multiple bilateral pulmonary nodules where were subsequently biopsied to be stage IV lung adenocarcinoma.

This study has limitations that must be acknowledged. First it is a retrospective review of prospectively acquired data and its conclusions may not apply to non renal donor populations. Second we have pathology results only from potential donors who underwent treatment at our institution. In addition, we evaluated a healthy population and thus our findings may not be applicable to patients with known co-morbidities which are contraindications for donor nephrectomy. We do not have follow up information of potential donors who sought work up and treatment at an outside facility. Despite these limitations, this is the largest report evaluating incidental findings in a healthy population using a high-quality imaging study. The CT protocol was uniform for all subjects and the reviewers were unaware of the characteristics of the subjects, making detection bias

unlikely. We used high-resolution imaging with specific phases optimized to detect not only solid organ and genitourinary findings, but also vascular abnormalities.

Irrespective of whether incidental findings are viewed as an advantage or disadvantage of pre-operative abdomen and pelvis CTA/CTU, it is unavoidable and the transplant radiologist will need to address the clinical acuity and triage the incidental findings. The pretest probability in an asymptomatic, low-risk population is low for clinically significant abnormalities. However, in a small percentage of cases, incidental findings warranted work-up. In our potential donor population, incidental findings requiring additional studies were seen in 4.5%. Therefore, pre-op CTA/CTU not only identifies vascular structures but may help detect unanticipated clinically important findings which may impact donation.

METHODS

Source Population

This is a HIPAA-compliant, institutional review board-approved observational single arm study of subjects undergoing renal transplant evaluation from June 1, 2006 to March 31, 2011. A total of 2,721 consecutive adult potential donors underwent donor screening which included medical and psychiatric assessment and once cleared for potential kidney donation, 1597 (58.7%) prospective donors underwent MDCTA/CTU for pre-surgical evaluation of renal vascular and parenchymal anatomy[22,23]. This was the final major step in the kidney donation process. The study cohort was further divided into two subcohorts: the donor and the non-donor subcohorts.

Abdominal CT Acquisition

All scans were obtained with either a 16 or 64 slice MDCT scanner (Somatom Sensation 16 or 64, Siemens Medical Solutions, Erlangen, Germany). The CT protocol was identical for all participants and included unenhanced and intravenous contrast-enhanced scans (arterial, nephrographic, and excretory phases) from the 11th thoracic vertebrae to iliac crest.

Assessment of Incidental findings

All scans were reviewed and incidental findings tabulated by one of three fellowship-trained abdominal radiologists, with 5-15 years of experience reading abdominal MDCTA/CTU. The diagnoses were made on the basis of CT finding characteristics of each lesion and pathology confirmation was available for seven patients. In addition, the presence of masses with malignant potential was recorded and follow-up surgical pathology results were collected, when available. Incidental findings were stratified by American College of Radiology (ACR) Managing Incidental Findings on Abdominal CT guidelines[8].

Statistical Analysis

We calculated the prevalence of each incidental finding in our population. Next, we calculated the overall prevalence rates of the most frequent incidental findings and performed a Fisher exact test or X^2 test for categorical variables between the cohort that did and did not undergo donor nephrectomy. All analyses were done using the statistical software STATA 11.2 (College Station, Texas) and statistics were considered significant at p-value of 0.05. References

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Table 1: Incidental findings categorized by “incidentaloma” per American College of Radiology Incidental Findings Committee White Paper on Managing Incidental Findings on Abdominal CT. Findings in bold require follow-up.

	No surgery (n=895)	Nx (n=702)	P value
Liver lesions			
0.5 cm-1.5 cm low attenuating without worrisome features, n=199	109 (12.2)	90 (12.8)	0.70
>1.5 cm	**0**	**0**	**1**
Pancreas cystic mass			
<2cm	**7 (0.8)**	**1 (0.1)**	0.9
2-3 cm	**2 (0.2)**	**0**	**0.50**
Kidney: solid enhancing renal mass (SRM)			
SRM <1 cm, n=1	1 (0.1)	0	1
SRM 1-3cm, n=4	**4 (0.4)**	**0**	**0.14**
Bosniak III renal cyst, n=1	**1** (0.1)	**0**	**1**
Bosniak IIF renal cyst, n=1	**1** (0.1)	**0**	**1**
Adrenal adenoma			
≤10 HU n=60	38 (4.2)	22 (3.1)	0.24
>10 HU 1-4cm	**1** (0.1)	**0**	**1**
Total , n=277 (17.3)	164 (18.3)	113 (16.1)	0.12
Patients with incidental findings warranting additional work-up, n=17 (1.1)	**16 (1.8)**	**1 (0.1)**	**0.001**

Table 2: Non-solid incidental findings of moderate or high clinical significance in the study cohort and subcohorts. Findings warranting additional work-up are in bold.

Study Cohort n=1597	Non- Donor Subcohort (n=895)	Donor Subcohort (n=702)	P value
Chest, n (%)			
Non-calcified >4mm lung nodule[1], n= 8 (0.5)	**7 (0.8)**	**1 (0.1)**	<0.0001
Interstitial lung disease, n=2 (0.1)	**2 (0.2)**	**0**	**0.5**
Lung arterial venous malformation, n= 1 (0.1)	**1 (0.1)**	**0**	**1.0**
Cardiomegaly, n= 1 (0.1)	**1 (0.1)**	**0**	**1.0**
Pleural effusion, n= 1 (0.1)	**1 (0.1)**	**0**	**1**
Liver, n (%)			
Fatty liver, n=180 (11.3)	133 (14.9)	47 (6.7)	<0.01
Hepatomegaly, n=7 (0.4)	**5 (0.6)**	**2 (0.3)**	**0.7**
Cirrhosis[2], n= 1 (0.1)	**1 (0.1)**	**0**	**1.0**
Kidney, n (%)			
Renal stone, n=79 (4.9)	81 (11.5)	61 (6.8)	<0.01
Horseshoe kidney, n=4 (0.2)	4 (0.4)	0	0.13
ADPKD[3], n=3 (0.2)	**3 (0.3)**	**0**	**0.26**
Medullary nephrocalcinosis, n=4 (0.2)	**4 (0.4)**	**0**	**0.13**
Unilateral small kidney, n=5 (0.3)	5 (0.6)	0	0.07
Renal fibromuscular disease, n=2 (0.1)	**2 (0.2)**	**0**	**0.5**
Medullary sponge / Tubular ectasia, n=34 (2.1)	20 (2.2)	14 (2.0)	0.86
Bilateral angiomyolipoma (possible tuberous sclerosis), n= 1 (0.1)	**1 (0.1)**	**0**	**1**
Pancreas, n (%)			
Chronic pancreatitis[4], n= 1 (0.1)	**1 (0.1)**	**0**	**1**
Annular pancreas**, n= 1 (0.1)**	1 **(0.1)**	0	1
Bladder, n (%)			
Urachal cyst, n= 1 (0.1)	**0**	**1 (0.1)**	**1**
Bladder wall thickening, n= 1 (0.1)	**1 (0.1)**	**0**	**1**
Female, n (%)			
Fallopian tube hydrosalpinx, n=4 (0.2)	**3 (0.3)**	**1 (0.1)**	**0.60**
Teratoma , n=7 (0.4)	**5(0.6)**	**2 (0.3)**	0.50
Septate uterus, n= 1 (0.1)	**1 (0.1)**	**0**	1
5 cm RLQ indeterminate cystic leison, n= 1 (0.1)	**1 (0.1)**	**0**	1
Hiatal hernia, n=42 (2.6)	32 (3.6)	10 (1.4)	0.008
>1cm lymph node, n=10 (0.6)	**6 (0.7)**	**4 (0.6)**	1
Right common iliac arterial stenosis (75%) , **, n= 1 (0.1)**	**0**	**1 (0.1)**	1

Total, n=464 (29.0)	300 (33.5)	164 (23.4)	<0.01
Total non-solid incidental findings requiring follow-up, n=56 (3.5)	**44 (4.9)**	**12 (1.7)**	<0.01

[1] Fleischner Criteria recommends 12 month follow up for >4mm non-calcified nodule in low risk group [2]Nodular liver concerning for cirrhosis
[3]Multiple renal cysts worrisome for ADPCKD
[4]Pancreatic calcifications with focal ductal dilatation suggestive of chronic pancreatitis

Table 3: Examples of incidentalfindings which would be considered relative and absolute contraindication for donor nephrectomy.

Absolute contraindications for donor nephrectomy	Absolute contraindications for donor nephrectomy
Bosniak III/IV renal cysts Horseshoe kidney Interstitial lung disease Noncalcified lung noudle > 4mm	Small renal masses 1-3 cm Cardiomegaly Cirrhosis Autosomal dominant polycystic kidney disease Chronic pancreatitis

Table 4: Findings with Procedures/ surgery performed and pathologic findings

Pt	Indications/ Imaging findings	Procedure or Surgery	Diagnosis
1	Gastric mass	Partial gastrectomy	Gastrointestinal stromal tumor
2	Pancreatic mass	Whipple	Serous adenocarcinoma
3	2 cm enhancing renal lesion	Partial nephrectomy	Angiomyolipoma
4	7 mm enhancing lesion	Partial nephrectomy	Benign renal cyst
5	Urachal cyst	Partial cystectomy	Urachal cyst
6	Bladder wall filling defect	Transurethral resection of bladder tumor	Grade 2 bladder cancer
7	Multiple small non-calcified right basal lung nodules	Right video-assisted thoracoscopy and biopsy	Stage IV lung adenocarcinoma

Figure 1: Total incidental findings (IF) in 1597 patients stratified by clinical concern.