

## ORIGINAL ARTICLE

# Economic and ethical impact of extrarenal findings on potential living kidney donor assessment with computed tomography angiography

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## Summary

To determine the prevalence and spectrum of extrarenal findings in a screening population of potential living kidney donors undergoing renal Computed tomography angiography (CTA) and evaluate their impact on subsequent patient management and imaging costs. Two radiologists retrospectively reviewed 175 consecutive renal CTA's performed for assessment of potential living kidney donors. Extrarenal radiological findings were recorded and classified according to high, medium, or low importance based on clinical relevance and the need for further investigations and/or treatment. The cost of additional imaging examinations was calculated using 2002 Canadian (British Columbia) reimbursements. There were 73 extrarenal findings in 71/175 (40.6%) of the potential kidney donors in the study population. Findings were categorized as of high clinical importance in 18 (10.3%) cases, including lung lesions, bowel tumors, and liver tumors and as medium importance in 31 (17.7%). Twenty-two (12.6%) individuals had findings categorized as low importance, probably of no clinical significance and requiring no follow-up. Further potential evaluation of the 49 patients (28%) with highly and moderately significant extrarenal findings may require an additional \$6137 (mean \$35.1 per each case of all the screened patients). Transplantation of a kidney from a living donor is an excellent alternative to cadaveric allografts. Potential living kidney donors are a highly selected population of healthy individuals, screened for significant past or current medical conditions before undergoing CTA. Despite this screening, potentially significant extrarenal findings (classified as high or medium importance) were revealed in 28% of patients. These patients may require further investigations and/or treatment. The referring physician and patient should be aware of such potentially high probability, which may require further nontransplant related evaluation and treatment. This has medical, legal, economic, and ethical implications.

## Introduction

Renal transplantation is the preferred treatment for end-stage renal disease. However, only a minority of patients receive transplants as a consequence of limited availability of cadaveric organs [1]. Living donor renal transplantation has been shown to be a safe surgical procedure with

excellent graft survival. The procedure also offers the opportunity to overcome the relative organ shortage.

Living kidney donor transplantations represent more than one half of renal transplants currently performed in North America [2,3] and 15–20% of renal allograft transplantations in Europe [4]. Preoperative assessment of renal anatomy is crucial during donor work-up. In addition to

renal function, the appearance of the renal arteries, supernumerary arteries and early branching are of particular importance for the decision on the side of nephrectomy. Ideally, preoperative imaging should also give sufficient information on venous and collecting system variants [4–7]. Computed tomography angiography (CTA), has been proven to be a powerful tool and has replaced digital subtraction angiography as the gold standard for the assessment of renal anatomy [7–12]. The candidates are a highly selected population of healthy individuals, carefully screened for significant past or current medical history and conditions. On CTA, the lung bases, entire abdomen and pelvis are imaged with thin-collimated images. The examination includes enhanced images of the scanned areas as well as angiography-like and urography-like reformatted coronal images. CTA allows visualization of the structures outside the urinary tract and may detect extrarenal abnormalities and disease. Although this provides an opportunity to detect unsuspected serious disease, the incidental detection of clinically significant findings may require additional tests that increases physician work load, patient anxiety and imaging costs. The prevalence and impact on the additional imaging costs of detecting extrarenal findings at CTA have not been evaluated. As a result, the additional cost incurred by detecting extrarenal findings has not been reported.

This report determines the prevalence and spectrum of extrarenal findings in a screening population of candidates for living kidney donors undergoing renal CTA. We evaluate the potential impact on subsequent patient management and imaging costs.

## Methods and materials

Our study group consisted of 175 consecutive patients (96 females, 79 males; age range, 23–68 years; mean age 42 years) who underwent CTA from February 2001 through August 2005 for assessment of potential living kidney donors. Prior to CTA all potential donors had completed a thorough evaluation to exclude any medical condition that would preclude kidney donation. The evaluation included collection of medical history data, physical examination by both a nephrologists and a transplant surgeon, renal ultrasound (US), chest X-ray, ECG, nuclear renography, viral serology, and urine collection to screen for proteinuria. All CTA's were performed on a four-row GE LightSpeed CT scanner (GEMS, Milwaukee, WI, USA). Two radiologists retrospectively reviewed these studies using a Windows-based workstation with conventional viewing software (eFilm Merge Technologies, Milwaukee, WI, USA). Findings related to the renal vessels, parenchyma, collecting system, ureters, bladder, prostate gland, and seminal vesicles were considered as urinary

and excluded from further analyses. Anatomic vascular variants of different types were excluded from the study as well. Abnormalities of all other structures and systems were considered as extrarenal radiological findings. These findings were classified using a modified version of a system used in a study of incidental extracolonic findings at CT colonography [13].

Absence of preceding knowledge of the abnormality by the patient or referring physician was used to define these findings as being truly incidental.

The results classified according to high, medium, or low importance based on clinical relevance and the need for further investigations and/or treatment.

Categories were as following:

1. Patients with findings of high clinical significance. These patients required prompt medical or surgical intervention or further workup. Findings included indeterminate masses of the bowel, liver, pancreas, adrenal, indeterminate lung nodules, lung cavitating lesions.
2. Patients with findings of moderate clinical significance. These patients required evaluation, treatment or follow-up at a later time. Examples of moderately clinically significant findings included gallstones, mesenteric and retroperitoneal lymphadenopathy.
3. Patients with findings of only low clinical significance. These findings were unlikely to require further imaging or intervention. Examples included liver cysts, splenic granulomas, hiatal hernia, diverticulosis, periumbilical hernias, rectus sheath hematoma, rugger jersey spine.
4. Patients without extrarenal findings.

The cost of additional imaging examinations was calculated using 2002 Canadian (British Columbia) Medical Association reimbursements [14] and included both professional and technical components. For liver and pancreatic masses the likely additional cost of further magnetic resonance imaging (MRI) evaluation (in case of equivocal results of the primary ultrasound examination) was also calculated. The cost of the workup of findings in groups I and II was estimated. For the purpose of comparison, the final results, presented in this article, were calculated in US Dollars.

## Results

The results are summarized in Tables 1–3.

There were 73 extrarenal findings in 71 of 175 (40.6%) potential kidney donors.

One hundred and four candidates didn't have any extrarenal findings.

Extrarenal findings, categorized as high clinical importance were found in 18 (10.3%) patients (Table 1). These included lung, liver, pancreatic, adrenal and bowel lesions, which demanded prompt further evaluation and

**Table 1.** Highly significant findings, potential follow-up, and costs.

	Findings at CTA	Number of patients	Follow-up radiologic examination	Number of follow-up procedures
Lung	Lung cavitation	1	CT chest	1
	Lung nodules	5	CT chest	5
Liver	Liver mass	7	US abdomen	7
			MRI liver*	7*
Pancreas	Pancreatic lesion	1	US abdomen	1
			MRI pancreas*	1*
Adrenal	Adrenal lesion	2	MRI adrenals*	2
Bowel	Duodenal mass	1	CT abdomen with oral contrast	1
	Jejunal mass	1	CT abdomen with oral contrast	1
Total		18		18
				26*

\*Indicates additional MRI scans for definite evaluation.

CT, computed tomography; CTA, computed tomography angiography; MRI, magnetic resonance imaging; US, ultrasound.

treatment. Two of the potential donors found unsuitable for donation. In three other cases the donation was significantly delayed because of the necessary additional evaluation and better donors were found.

Twenty-six further diagnostic procedures were required to evaluate these lesions, predominantly consisting of Ultrasound, CT and MRI examinations. Total estimated follow-up radiologic costs in this group are \$6993.

Table 2 summarizes lesions of medium importance in thirty-one (17.7%) potential kidney donor. The findings included: mesenteric and retroperitoneal lymphadenopathy, hypodense liver lesions, gall bladder findings (stones, polyp, wall thickening), mucocele of appendix. In two cases the donation was significantly delayed because of the evaluation. In two other cases the final decision regarding the donation is pending. Additional radiologic imaging tests at a total cost of \$3199 would be required to further investigate these findings.

The results of the further evaluation of the extrarenal findings in these two groups were: in two of the potential donors malignant tumors (adenocarcinoma and squamous cell carcinoma) were found. Eighteen had benign tumors (benign gastrointestinal stromal tumor (GIST), adenomas, focal nodular hyperplasia, hemangiomas) or

benign conditions (adenomyomatosis of the gallbladder, cysts). Twelve of the potential donors were found to have chronic granulomatous disease and chronic infection. Data of the final results of the evaluation of two potential donors is unavailable.

Twenty-two (12.6%) individuals had 24 findings categorized as low importance (Table 3). By definition, no additional follow-up testing was required. However, awareness of these findings including diverticulosis, hiatal hernia, duodenal diverticulum, rectal sheath hematoma, paraumbilical hernias, liver cysts, splenic granulomas, hemangioma and bony findings was important information for their medical records.

Considering the findings in all three categories, a total of 49 patients (28%) – with findings of high and medium clinical importance–required further diagnostic imaging tests. Based on Canadian (British Columbia) Medical Association Guide to Fees (2002), the estimated total cost of the necessary follow-up imaging studies is \$6137. This sum, divided between all 175 screened potential kidney donors adds a potential cost of \$35.1 to each study. The likely potential need for a MRI scan for definite diagnosis in eight patients increases the likely additional estimated cost up to \$58.2 per each case.

**Table 2.** Moderately significant findings, follow-up, and costs.

	Findings at CTA	Number of patients	Follow-up radiologic examination	Number of follow-up procedures
Gall Bladder	GB stones	3	US abdomen	3
	GB polyp	1	US abdomen	1
	Thickening of GB wall	1	US abdomen	1
Liver	Hypodense liver lesion	16	US abdomen	16
Mesentery and retroperitoneum	lymphadenopathy	9	CT abdomen	9
Bowel	Mucocele of appendix	1		
Total		31		30

CT, computed tomography; CTA, computed tomography angiography; US, ultrasound.

**Table 3.** Low significant findings.

Findings at CTA		Number of findings (patients)
Liver	Liver cyst	11
Spleen	Spleen granulomas	1
	Spleen hemangioma	1
Bones	Bilateral posterior L5 defect	1
	Rugger jersey spine	1
Abdominal wall	Periumbilical hernia	4
	Rectus sheath hematoma	1
Gastro-intestinal tract	Hiatal hernia	1
	Large bowel diverticulosis	2
	Duodenal diverticulum	1
Total		24 (22)

CTA, computed tomography angiography.

## Discussion

Living donor renal transplantation is a commonly performed surgical procedure [4]. Potential living kidney donors are a highly selected population of healthy individuals, carefully screened for significant past or current medical conditions. CTA has become the gold standard for preoperative assessment of renal anatomy and is crucial for donor work-up [7–12].

The ability of CTA to image extraordinary structures may lead to the serendipitous finding of previously undiscovered conditions. Thus, serious asymptomatic disease may be detected at an early and potentially curable stage [15] and may therefore improve patient outcomes.

In our study, 28% of screened donor candidates had extrarenal findings, considered of high (10.3%) and medium (17.7%) clinical importance. The detection of these findings may lead to additional tests and increased imaging costs.

Of note, 12.6% potential living kidney donors had inconsequential extrarenal findings which did not require additional imaging studies or other interventions.

Incidental findings on CT examinations and their economic impact have been evaluated for CT colonography [15–22] and CT urography for patients with hematuria [23].

Following the approach proposed in the works of Gluecker [13] and Sonnenberg *et al.* [24] we estimated the average costs based on professional reimbursement and mean technical and facility costs for CT of the abdomen, US abdomen and liver, pancreatic and adrenal MRI. The overall short-term cost for the additional radiologic examinations was \$6137 (with likely increase up to \$10192), thus adding at least \$35.1 to the average cost of the examination.

Several authors studied the economic effect of incidental findings in CT examinations. Using Medicare reimbursement rates they revealed an average additional cost

of \$28 [21,22] - \$34.33 [13] per CT colonographic examination and \$41.37 per CT Urography [23].

These results are compatible with ours, calculated on the base of Canadian (British Columbia) reimbursements rates, which included both professional and technical components.

Nonmonetary effects (including patient anxiety, concern and morbidity) associated with follow-up and treatment of extrarenal findings also must be considered. The awareness of findings of even medium or low importance might create distress for the patient such that the referring physician must initiate further work-up for these findings. This could potentially result in additional costs and morbidity. Lerman *et al.* [25] showed significantly elevated breast cancer screening - related anxiety, despite the fact that a malignant lesion was ruled out by follow-up studies. Berlin [26] pictorially described the patient with incidentally found lesions who “didn’t want to sit around thinking ... (he) had a malignant lesion” and then undergoing further surgery, hospitalization and postsurgical convalescence. Eventually, incidental findings may be compared with the opening of Pandora’s box [26]. It was the mythic box which contained the human ills of the world (and, probably, different types of potential allegations), which escaped when the box was opened. Thus, potential legal and ethical aspects of incidental findings are important and should be considered [26,27].

Different ethical implications of incidental findings arise from the radiologist’s responsibility to communicate results of radiographic examinations to patients and referring physician. Physicians are to inform patients of the potential consequences of CTA, explaining to potential kidney donors the myriad uncertainties that pertain to potential detection of incidental findings.

This report is limited by calculation of only potential cost of additional radiologic evaluation of incidental extrarenal findings. Future studies, which would include the value of patient and caregiver time, and resources devoted to subsequent evaluation and treatment as the result of the extrarenal CTA findings to calculate both direct and indirect costs are required. Another limitation was inability to calculate the exact costs of the rejection or delay in kidney donation which were the result of incidental extrarenal findings. It is clear that such rejection and delay increases the cost of the pre-transplantation work-up and has negative psychological impact.

In conclusion, despite previous screening, potentially significant extrarenal findings may be revealed in 28% of CTA examinations of potential living kidney donors. These patients may require further investigations and treatment.

The referring physician and the patient should be aware of the medical, legal, economic and ethical implications of renal CTA in a potential donor population.

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