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Differences in American and International Guidelines Regarding Use of Kidney Stone Formers as Living Kidney Donors

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Abstract

Purpose of review: Traditionally, nephrolithiasis was considered a relative contraindication to kidney donation because of a risk of recurrent stones in donors and adverse stone-related outcomes in recipients. However, the scarcity of organs has driven the transplant community to re-examine and broaden selection criteria for living donors with stones. In this review, we summarize and contrast the guidelines published by various prominent national and international societies on this topic.

Recent findings: Although recent iterations of living donor guidelines are less stringent with respect to nephrolithiasis than those published in the 1990s, there is little consensus among American and international transplant society guidelines regarding selection criteria for potential kidney donors with nephrolithiasis.

Summary: The lack of evidence-based guidelines deters transplant centers from implementing selection criteria to accept donors with nephrolithiasis and discourages studies of outcomes in donors with nephrolithiasis and their recipients. In addition to drawing attention to the disparities in prevailing guidelines, we put forth several questions that must be answered before generalizable criteria for selection of donor with nephrolithiasis can be developed.

Keywords

kidney stones; nephrolithiasis; kidney donor; donor nephrectomy; kidney transplantation; acute kidney injury; end-stage renal disease

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Introduction

Compared with dialysis, kidney transplantation affords longer patient survival and superior quality of life while incurring considerably lower health care costs. It is the treatment of choice for most patients with end-stage renal disease (ESRD)[1–5]. However, the demand for transplantable organs far exceeds the supply. Currently, there are approximately 95,000 patients on the United States kidney transplant wait-list while only 19,850 patients received a kidney transplant in 2017[6]. This calamitous scarcity of organs has driven the transplant community to re-examine and broaden selection criteria for both living and deceased donors[7]. Several clinical approaches to minimize deceased donor organ discard rates are increasingly being utilized[7].

Living donor kidney transplants account for approximately 30% of the transplants performed annually in the United States[6]. Living donor transplants offer better patient and allograft survival when compared with deceased donor transplants, especially when performed pre-emptively (prior to initiation of dialysis)[8–10]. These superior outcomes, together with the snowballing wait-list have focused attention on living donation as a means to increase the supply of organs for transplant candidates[11, 12]. Reflecting a trend towards acceptance of some organs that were previously considered unsuited for transplantation, many transplant centers are now adopting standards that allow “complex living donors” to undergo donor nephrectomy[12, 13]. Living donors with obesity, hypertension, and nephrolithiasis, conditions that are themselves associated with kidney disease, are considered complex donors[12].

Nephrolithiasis is a global disease with increasing prevalence[14]. The lifetime prevalence of stones is approximately 10% among men and 7% among women[15]. Symptomatic kidney stones have been linked to many systemic conditions including hypertension, metabolic syndrome, and development of ESRD[16–18]. Donors with nephrolithiasis (with either a history of symptomatic stones or those who are incidentally found to have kidney stones during evaluation for living kidney donation) serve as exemplars of complex living donors. Traditionally, nephrolithiasis was considered a relative contraindication to kidney donation, both because of a risk of recurrent stones in donors and adverse stone-related outcomes in recipients[19, 20]. Guidelines published in 1996 by the Ad Hoc Clinical Practice Guidelines Subcommittee of the Patient Care and Education Committee of the American Society of Transplant Physicians recommended candidates be allowed to donate if they had passed no more than one stone in the past, had inactive disease for at least 10 years, had a normal metabolic evaluation and were found to have no stones on donor radiographic studies[20]. Introduction of computed tomography (CT) angiography for screening of living kidney donor candidates has led to an increase in incidental detection of kidney stones[21]. However, the clinical significance of many of these findings is unclear[21]. Increased detection of asymptomatic solitary stones on CT angiography and advances in endourologic techniques for treating donors and recipients who develop nephrolithiasis have led to an evolution of attitudes regarding selection criteria for living kidney donors with stones over the last two decades[21].

More recent iterations of living donor guidelines are less stringent with respect to nephrolithiasis[19, 22]. In 2005, the Amsterdam Forum on the care of the live kidney donor suggested allowing asymptomatic potential donors with a single incidentally discovered stone (on radiography during evaluation for kidney donation) to donate if the current stone was less than 15 mm in size and metabolic profile was normal[13]. However, selection criteria at transplant programs across the United States are highly variable given the uncertainty due to the absence of reliable outcomes data in donors with nephrolithiasis and their recipients[23].

Two living donor surveys conducted about a decade ago drew attention to the need for evidence-based guidelines, and data from these surveys serve to inform selection criteria for donors with nephrolithiasis at many transplant centers[23, 24]. A survey of national living donor evaluation practices conducted by Mandelbrot et al in 2007 reported that 23% of transplant centers in the United States excluded candidates from donation if they had a history of stones, 19% accepted candidates with a history of stones if they had none currently present, and 53% accepted candidates with a history of stones if they had none currently present and had normal metabolic studies[23]. 5% of the centers reported that they had no policies regarding potential living kidney donors with nephrolithiasis[23]. Another survey, looking exclusively at transplant center practices pertaining to living kidney donors with nephrolithiasis, was undertaken by Ennis et al in 2007–2008. They reported that 77% of responding centers allowed stone formers to donate and that 40% of centers reported that their attitude towards accepting donors with kidney stones has changed over the last 5–10 years. The authors of that survey emphasized the need for a study to formally evaluate the outcome of stone formers who donate a kidney in order to systematically examine whether appropriately selected stone formers can safely donate[24]. In the decade since these surveys, additional data regarding prediction of stone recurrence, the distinction in clinical characteristics between patients with symptomatic stones and those with incidentally discovered stones, and outcomes in donors with nephrolithiasis and their recipients have become available[17, 25, 26]. For example, Rule et al devised a prediction tool to identify kidney stone formers at greatest risk for a second symptomatic stone[25]. A risk calculator that predicts individualized risk at 5, 10 and 20 years after a first episode is available online[25, 27].

Studies to date suggest that hazards of nephrectomy to the health of the donor are very modest although not entirely absent[28, 29]. However, similar safety data regarding outcomes in complex living donors are sparse, posing a significant challenge to transplant professionals in counseling and providing care for such donors[12, 24]. Strang et al performed a systematic review of medical literature published between 1966 and 2007 to assess stone-related morbidity in kidney donors with asymptomatic kidney stones and their recipients. Although they found that most studies were limited by small sample size and short duration of follow-up, they concluded that the risk of stone recurrence and related morbidity in kidney donors is low but not insignificant. In the absence of long-term outcomes data demonstrating safety in donors with kidney stones and their recipients with donor gifted nephrolithiasis, Strang et al recommended that those evaluating donor eligibility must remain current with transplant guidelines around the world. However, a perusal of the profusion of national and international transplant society guidelines indicates

that there is hardly any consensus among them regarding selection criteria for potential kidney donors with nephrolithiasis. The lack of evidence-based, widely accepted guidelines not only deters transplant centers from implementing selection criteria to accept donors with nephrolithiasis but also discourages future observational and controlled studies evaluating outcomes in donors with nephrolithiasis and their recipients. To draw attention to these issues, in this review, we summarize and contrast the guidelines published by various prominent American and international societies on this topic.

American Society of Transplant Physicians (ASTP)

The Ad Hoc Clinical Practice Guidelines Subcommittee of the Patient Care And Education Committee of the American Society of Transplant Physicians (ASTP) published living donor evaluation guidelines in 1996[20]. Nephrolithiasis was deemed to be at least a relative contraindication to living kidney donation given a future risk of kidney injury due to recurrent stone-related obstruction and infections[20]. They also noted that inadvertent transplantation of a kidney with stones places the recipient at risk[20]. Kasiske et al suggested that a stone former could be allowed to donate if he or she has passed only one stone, has stone disease that has been inactive for greater than 10 years, and no kidney stones were present on current radiographic studies. They recommended that such individuals should be screened for metabolic abnormalities (using a 24-hour urine sample to assess urinary volume, calcium, citrate, uric acid, and oxalate excretion) to ensure that there are no risk factors for active stone disease. Kasiske et al state that donor candidates with detectable metabolic abnormalities should “probably be excluded from donation”[20]. These early guidelines stressed the importance of lifelong medical follow-up including periodic stone risk assessment and medical treatment, to alleviate any risk factors for stone formation that are subsequently discovered[20]. The Ad Hoc Clinical Practice Subcommittee implied through these guidelines that stones discovered incidentally during donor evaluation are a contraindication to kidney donation irrespective of size or number. These early recommendations formed the framework upon which future society guidelines were developed.

Amsterdam Forum

The Amsterdam Forum held in April 2004 brought together kidney transplant physicians and surgeons to develop an international standard of care position statement of The Transplantation Society (TTS) regarding the care of live kidney donors[13]. The Forum put forth recommendations that have since become well known and widely cited, regarding the evaluation of potential kidney donors with nephrolithiasis, and relaxed some restrictions detailed in the guidelines published by ASTP[19].

Asymptomatic potential donors with a history of a single stone as well as those with a single radiographically discovered stone (<1.5 cm or that is potentially removable) were considered suitable if they met the following requirements[13]:

- No hypercalciuria, hyperuricemia, or metabolic acidosis.
- No cystinuria or hyperoxaluria.

- No urinary tract infection.
- Multiple stones or nephrocalcinosis are not evident on CT scan.

Nephrocalcinosis on X-ray or bilateral stone disease, and stone types that have high recurrence rates and are difficult to prevent, were listed as contraindications for kidney donation. The risk of recurrence was considered prohibitive for donation in the following conditions: cystine stones, struvite stones, stones in the setting of inflammatory bowel disease, recurrent stones while on appropriate treatment, stones associated with inherited or systemic disorders such as primary or enteric hyperoxaluria, distal renal tubular acidosis, and sarcoidosis. The position statement cautioned that younger donors (age 25–35) have longer exposure to the possibility of stone recurrence. Finally, the Amsterdam Forum commented that *ex vivo* ureteroscopy is a feasible way to render a stone-bearing kidney stone free, without compromising ureteral integrity or renal allograft function.

Kidney Disease: Improving Global Outcomes (KDIGO)

Kidney Disease: Improving Global Outcomes (KDIGO) is a global organization, governed by an international volunteer executive committee, that develops and implements evidence-based clinical practice guidelines for kidney disease. The 2017 KDIGO clinical practice guidelines on the evaluation and care of living kidney donors set forth the following recommendations for the evaluation and selection of potential kidney donors with stones[22].

- Donor candidates should be asked about prior kidney stones, and related medical records should be reviewed if available.
- The imaging performed to assess anatomy before donor nephrectomy (e.g. computed tomography angiogram) should be reviewed for the presence of kidney stones.
- Donor candidates with prior or current kidney stones should be assessed for an underlying cause.
- The acceptance of a donor candidate with prior or current kidney stones should be based on an assessment of stone recurrence risk and knowledge of the possible consequences of kidney stones after donation.
- Donor candidates and donors with current or prior kidney stones should follow general population, evidence-based guidelines for the prevention of recurrent stones[22].

KDIGO permits potential donors with asymptomatic kidney stones that are incidentally detected on imaging, as well as donor candidates with prior or current kidney stones, to donate. The guidelines make certain specific recommendations in each of these instances (Table 1). However, in the case of incidentally detected kidney stones, KDIGO makes no suggestions regarding the allowable number, laterality, or size of stones. KDIGO does not comment on the time that has to elapse after an episode of symptomatic stones following which a potential donor can undergo donor nephrectomy. KDIGO also does not explicitly state whether recurrent stone formers can be allowed to donate and takes no position

regarding treatable metabolic abnormalities detected on the 24-hour urine collection (e.g. hypocitraturia, primary hyperparathyroidism)[22].

Organ Procurement and Transplantation Network (OPTN)

United Network for Organ Sharing (UNOS) is an organization that administers the Organ Procurement and Transplantation Network (OPTN) in the United States. OPTN policies govern operation of all member transplant hospitals, organ procurement organizations (OPOs) and histocompatibility labs in the U.S. The current OPTN policy for medical evaluation of living kidney donors states that potential donors with a history of kidney stones or a kidney stone >3 mm detected on radiographic imaging must have a 24-hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine and sodium[30]. OPTN policy states that anatomic assessment must be made, presumably by imaging, to determine if kidneys have masses, cysts or stones[30]. OPTN does not provide guidance regarding number or laterality of incidentally detected stones and makes no recommendations about nephrolithiasis symptom-free wait time or management of metabolic abnormalities diagnosed by analysis of 24-hour urine collection.

American Society of Transplantation (AST) Live Donor Community of Practice

The American Society of Transplantation (AST) Communities of Practice (COPs) are specialty-area focused groups within AST[31]. The current AST Live Donor COP recommendations address the question of whether potential kidney donors with stones should be allowed to donate[32]. They cite data that suggest that kidney donors with small asymptomatic stones (2–3mm) have an incidence of stone-related events of 0–2% at 2 years follow up, a low incidence compared to 23% at 2.6 years of follow-up among patients with small (4 mm) asymptomatic stones in the general population[26, 32–35]. The AST live donor COP statement infers that this low frequency recurrence is perhaps due to the donors being healthier overall than the general population[32]. They recommend allowing kidney donors with small incidental renal stones to donate if they are left with the stone-free kidney and the metabolic stone work-up is negative. No guidance regarding the number of stones or role of *ex-vivo* ureteroscopy to remove stones before transplantation is provided. The AST Live Donor COP recommends that potential donors with symptomatic stone disease be considered if they have a distant history of having passed a single stone, currently have no detectable stones on imaging and have negative metabolic testing[32]. They suggest using the recurrence of kidney stones (ROKS) online calculator to help guide decision making[27, 32]. However, the AST COP recommendations do not define how long a potential kidney donor with a history of symptomatic stones must be symptom-free before donation. The specific tests to be ordered as part of metabolic stone work-up are not detailed in the recommendations.

British Transplantation Society (BTS)

The 2018 BTS Guidelines for Living Donor Kidney Transplantation suggest that potential donors with a limited history of previous kidney stones, or small stone(s) on imaging may be

allowed to donate provided there have no significant metabolic abnormalities[36]. Notably, these guidelines recommend consultation with a specialist in kidney stone disease if metabolic abnormalities are diagnosed. In appropriate donors with unilateral kidney stone(s) the BTS recommends transplantation of the stone-bearing kidney in order to leave the donor with the stone-free kidney unless vascular anatomy and split renal function assessment preclude this[36]. The BTS stresses the importance of post-donation follow up and counseling of the donor and recipient regarding the risks and consequences of stone-related morbidity[36].

European Best Practice Guideline (EBPG)

In 2015, the European Best Practices Guidelines (EBPG) group put out guidelines that discuss criteria to be used to select living kidney donors to optimize the risk/benefit ratio of their donation in potential donors with hypertension, obesity, impaired glucose tolerance, proteinuria, hematuria, and older donors. However, they do make any specific recommendations regarding donors with nephrolithiasis[37].

Discussion

An appraisal of the subject of nephrolithiasis in potential kidney donors leads us to the crossroads of several onerous topics in transplantation, nephrology, and ethics. Despite advances in transplant immunology, surgery and therapeutics along with a contemporaneous increase in awareness of organ donation and transplantation, there continues to be a gap between supply and demand of organs[38]. The transplant community is in a constant quest to enhance organ donation. When selected with careful scrutiny, living donors with nephrolithiasis and other “complex donors” may help bridge the yawning gulf of organ shortage. Concerns regarding recurrence in a single kidney and the attendant risk of obstruction causing acute renal failure in donors, and to a lesser extent, similar concerns in recipients of living donor kidneys due to passage of stones left in situ (“donor-gifted lithiasis”) are impediments to broader acceptance of donors with nephrolithiasis[19, 24].

Reliable prediction of the risk of stone recurrence in the remnant kidney in donors can enable donors, transplant nephrologists, and transplant surgeons to make informed decisions. However, such information is all too often lacking. A scarcity of outcomes data in donors with nephrolithiasis and the recipients of their kidneys is another reason for underutilization of these complex living donors[12, 19]. Several questions must be answered before widely accepted and generalizable criteria for selection of donor with nephrolithiasis can be developed:

- Should potential kidney donors with nephrolithiasis be excluded if no treatable metabolic abnormality (e.g. hypocitraturia, primary hyperparathyroidism) is detected during the screening process, even if they qualify based on other stone-related criteria?
- Has the availability of modern, flexible endourologic treatments changed the practical risk of the occurrence of a stone in a solitary kidney? If so, should that fact influence criteria for donor selection?

- How long do potential donors with a history of a single symptomatic stone need to be inactive (with no symptomatic stones) before they can undergo donor nephrectomy? Does the time interval matter?
- In potential donors who are incidentally found to have kidney stones on imaging, what is the maximum allowable number of stones; what is the largest acceptable stone size; and does extraction of stones via *ex vivo* ureteroscopy/pyelolithotomy prior to implantation improve outcomes?
- Are the risks of having recurrent stones in a solitary kidney after donation increased or decreased as the result of the nephrectomy?
- Is obtaining 24-hour urine risk panels in potential donors beneficial? How should the results influence the criteria for selecting donors?
- What post-donation fluid intake, dietary regimens and follow-up protocols (screening for metabolic abnormalities by 24-hour risk profile, imaging) minimize stone-related morbidity in donors?

Furthermore, ethical questions abound, since donors may sometimes wish to proceed with surgery despite a disproportionate risk to their health[12]. In such a scenario, preserving the autonomy of donors while also upholding the principles of beneficence to the recipient and non-maleficence to the donor is a difficult balance to strike[12]. These uncertainties have led to evolving professional society guidelines and significant variations in practices pertaining to selection of living kidney donors with nephrolithiasis across transplant centers in the United States[13, 20, 22, 24].

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Key Points

- To alleviate the shortage of organs, many transplant centers are now adopting standards that allow potential living donors with nephrolithiasis to undergo donor nephrectomy.
- There is little consensus among national and international transplant society guidelines regarding selection criteria for potential kidney donors with nephrolithiasis.
- Prospective studies that quantify risk of stone related morbidity in donors with nephrolithiasis are needed to inform future professional society guidelines that can be universally adopted.
- Preserving the autonomy of donors while ensuring beneficence to the recipient and non-maleficence to the donor is paramount.

Figure 1: Amsterdam Forum on the Care of the Live Kidney Donor - criteria for living kidney donors with nephrolithiasis (13).

*Cystine stones, struvite stones, stones in the setting of inflammatory bowel disease, recurrent stones while on appropriate treatment, stones associated with inherited or systemic disorders such as primary or enteric hyperoxaluria, distal renal tubular acidosis, and sarcoid.

Table 1

Potential donors with history of stones	ASTP, 1996 (20)	Amsterdam Forum, 2005* (13)	KDIGO Guidelines, 2017 (22)	OPTN/UNOS, 2018 (30)	AST COP, 2018 (32)	BTS, 2018 (36)
	<p>Allowed to donate if they passed only one stone, had stone disease that has been inactive for > 10 years, no kidney stones were present on current radiographic studies. and</p> <p>Have no evidence of the following metabolic abnormalities on 24-h urine analysis: hypercalciuria, hypocitraturia, hyperuricosuria, hyperoxaluria.</p> <p>Not considered candidates for donation.</p>	<p>Currently asymptomatic potential donors with history of single stone may donate if:</p> <ul style="list-style-type: none"> • No hypercalciuria, hyperuricemia, or metabolic acidosis. • No cystinuria or hyperoxaluria. • No urinary tract infection. • Multiple stones or nephrocalcinosis are not evident on CT scan. 	<p>May donate based on assessment of stone recurrence risk and knowledge of possible consequences of kidney stones after donation.</p> <p>When stones are present but do not preclude donation, the affected kidney should be used for donation.</p> <p>KDIGO recommends: Medical and dietary history, serum chemistries, urinalysis for donors with newly diagnosed stones.</p> <p>Check PTH when primary hyperparathyroidism is suspected, stone analysis when stone is available.</p> <p>Obtain and review imaging.</p> <p>Metabolic testing in high-risk donors and recurrent stone formers.**</p>	<p>Must have a 24-hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine and sodium.</p>	<p>Kidney donors with small incidental renal stones may donate as long as they are left with the stone-free kidney and the metabolic stone work-up is negative.</p>	<p>In the absence of a significant metabolic abnormality, potential donors with a limited history of previous kidney stones may be considered as potential kidney donors.</p> <p>Full counselling of donor and recipient is required along with access to appropriate long-term donor follow-up.</p> <p>Potential donors with metabolic abnormalities detected on screening should be discussed with a specialist in renal stone disease.</p>
Potential donors with asymptomatic stones seen on imaging		<p>Asymptomatic potential donors with single current stone that is <1.5 cm or potentially removable, may donate if:</p> <ul style="list-style-type: none"> • No hypercalciuria, hyperuricemia, or metabolic acidosis. • No cystinuria or hyperoxaluria. • No urinary tract infection. • Multiple stones or nephrocalcinosis are not evident on CT scan. 	<p>Does not consider stones incidentally detected on imaging a contraindication for donation.</p> <p>KDIGO notes that 5% of individuals have asymptomatic kidney stones on CT angiography and CT scans may detect small calcifications including Randall's plaques which are 1 to 2 mm calcifications of uncertain prognostic significance.</p>	<p>Potential donors with kidney stone >3 mm detected on radiographic imaging must have a 24-hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine and sodium.</p>	<p>May consider accepting donors with a distant history of a single passed stone, as long as there are no stones on current imaging and the metabolic testing is negative.</p>	<p>In the absence of a significant metabolic abnormality, potential donors with small renal stone(s) on imaging, may still be considered as potential kidney donors.</p> <p>In appropriate donors with unilateral kidney stone(s) the stone-bearing kidney can be considered for donation (if vascular anatomy and split kidney function permit) in order to leave the donor with a stone-free kidney after donation.</p>
Ex-vivo Removal of Kidney Stones		<p>Ex vivo ureteroscopy is a feasible way to render a stone-bearing kidney stone free, without compromising ureteral integrity or renal allograft function.</p>	<p>KDIGO comments that there are reports on the safety and success of ex vivo ureteroscopy to remove stones from explanted donor kidneys before transplantation but makes no recommendations for or against this practice.</p>			

* Contraindications to donation: Nephrocalcinosis on X ray or bilateral stone disease; stone types that have high recurrence rates and are difficult to prevent.

** Metabolic testing should consist of one or two 24-hour urine collections obtained on a random diet and analyzed at minimum for total volume, pH, calcium, oxalate, uric acid, citrate, sodium, potassium and creatinine.