

## ORIGINAL ARTICLE

# Can value for money be improved by changing the sequence of our donor work-up in the living kidney donor programme?

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## Keywords

cost-effective, donor work-up, kidney, living donor, transplantation.

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## Summary

The aim of the study was to identify procedures of maximum importance for acceptance or rejection of kidney donation from a living donor as well as making the process more cost-effective. We identified all potential living related donors who were examined during the period between January 2002 and December 2006 at our department. The cost in euro (€) for the programme was estimated using the Danish diagnosis-related group-system (DRG). The donor work-up programme was described. One hundred and thirty-three potential donors were identified; 66 male- and 67 female subjects, median age of 52 years (range 22–69). Sixty-four participants were rejected as donors. Abdominal CT-scan with angiography and urography ruled out 22 of the above 64 potential organ donors; thus, 48% of the volunteers for living kidney donation were unsuited for donation. Abdominal CT-scan with angiography and urography was the procedure identifying most subjects who were unsuited for kidney donation. A rearrangement of the present donor work-up programme could potentially reduce the costs from €6911 to €5292 per donor – saving 23% of the costs. By changing the sequence of examinations, it might be possible to cut down on time spent and number of tests needed for approving or rejecting subjects for living kidney donation.

## Introduction

Renal transplantation is the preferred treatment of end-stage kidney disease. There is a general shortage of kidneys available for transplantation from deceased donors [1]. This calls for an increase in other sources for recruiting organs such as using marginal donor kidneys aiming at extending the donor pool [2]. The living kidney donor programme represents a significant contributor and a very evident alternative to expanding the overall pool of donated kidneys in Europe and North America [3–5]. A total of 6036 living kidney transplantations were done out of 16 623 renal transplantations performed in 2007 in North America [1].

The living renal donor programme is a safe and suitable alternative to deceased kidney transplantation [6].

The surgical procedure is well-established and the graft survival is proven to be excellent [7]. The donor work-up is however time-consuming for the potential donor and the transplantation centre performing the assessment of the potential kidney donor [8].

Optimally the work-up should be as smooth as possible and performed at a pace according to the wishes of the donor. Yet it needs to be cost-effective and thorough [9]. The organization of most work-up programmes reflects the idea of starting with the simple examinations followed by the more complex and costly examinations [10,11]. There is very little knowledge about the total costs and workload generated by a living kidney donor programme. To establish evidence in this matter, it is essential to make cost-effectiveness analysis of the donor work-up programmes conducted so that most value for money can

be achieved in the process of finding potential donors. Saunders *et al.* [8] concluded that the donor yield is low and the workload is significant in a common living donor programme. The optimal design of a living donor programme is not known at present because of lack of evidence concerning donor work-up and exact requirements for approving or disqualifying a potential organ donor [10,11]. The field is thus characterized by local practice at every transplantation centre and little solid evidence. There is no knowledge regarding the preferences of the potential donors concerning invasive tests done or time spent on the donor work-up. It is however presumed that the potential donors wish to limit the time spent and the amount of invasive procedures done without compromising the accuracy of the donor work-up.

The aim of this study was to identify examinations or procedures of maximum importance for acceptance or rejection from kidney donation, and to estimate the cost of our programme.

## Methods

The study population comprised all potential living related donors who were examined over a 5-year period between January 2002 and December 2006 at our department a total of 133 potential donors, 66 male- and 67 female subjects with a median age of 52 years (22–69 years). The medical files were evaluated retrospectively. Demographic, clinical and paraclinical data were collected from the subjects' medical files. The historical donor work-up was conducted according to the sequence outlined in the flow chart presented in Fig. 1.

In Denmark, all living related donors receive full coverage of costs related to the donor work-up and the hospitalization related to the kidney donation. Loss of income

during this process is thus covered by the Danish health-care and social system.

The use of a psychological work-up as part of the donor work-up in a living related donor programme is not common practice in Denmark and is thus not used as a standard in our setting.

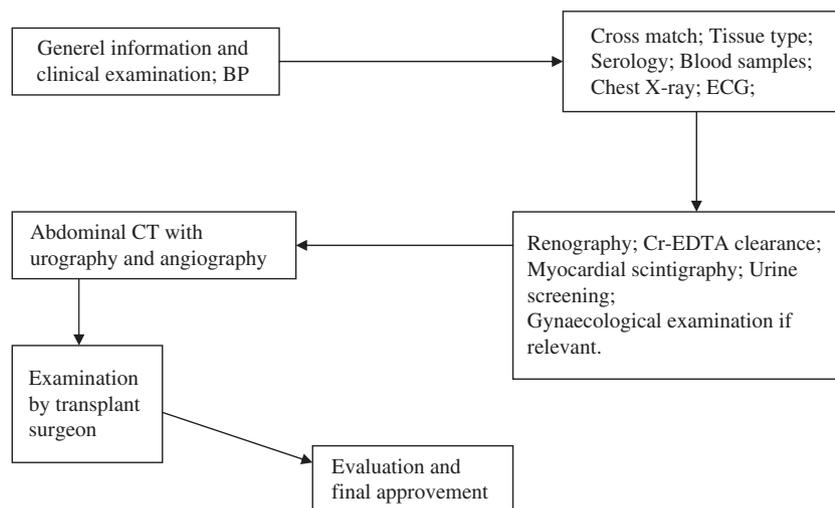
All potential donors had reported themselves healthy, and without ABO incompatibility toward the recipient. In the analysis, the potential kidney donors were divided into two groups depending on whether or not they were approved for donation through the donor work-up programme and donation thus realized.

We identified the reason and the procedure that rejected the potential donor. The current donor work-up programme was evaluated with respect to cost in euro and time spent on the clinical and paraclinical work. We used the Danish DRG-system to identify the cost for every step during the donor work-up programme. We then calculated the total cost for the 5-year period (2002–2006) and a final cost for one single living kidney donor ready for donation. This was calculated as the total cost in euro for all subjects that went through the donor work-up programme divided with the final number of potential donors ready for donation. The cost of one subject completing the whole work-up programme was also calculated.

The time spent on donor work-up was recorded as the time from first visit at the out-patient clinic until the final approval or rejection as donor. Time spent waiting to donate a kidney was recorded as time from approval until surgery was performed.

Our traditional work-up programme for living kidney donors started with compilation of general information and recording of the medical history and vital signs, which is done at the out-patient clinic. Blood pressure

**Figure 1** General information: written and oral; Blood pressure (BP); Serology: Wasserman reaction and antibody screen test against HIV, Hepatitis B and C virus, Epstein barr, Varicella zoster- and Herpes simplex viruses; Blood samples: common screen with blood glucose and prostatic antigen if relevant; Electrocardiogram (ECG); Urine screening: 24 h urine collection for protein and clearance  $\times 2$ , urine culture and microscopy; Examination by transplant surgeon: Clinical examination and information about the surgical procedure.



(BP) was measured and accepted as normal if it was lower than 140/90 in the out-patient clinic. If needed, a 24-h BP test was conducted and a mean daytime BP of 135/85 and lower was accepted as normal. This is followed by ordinary laboratory analysis including screening for proteinuria and haematuria, a cross-match and tissue-typing.

If these examinations did not reveal any abnormalities, the measurements of GFR by 51-Cr-EDTA clearance and renography followed. Renal function was accepted as adequate if it was within the limits stated in the 'United Kingdom Guidelines for Living Donor Kidney Transplantation' from the year 2000 [12]. The work-up was finalized by an abdominal CT-scan with combined angio sequence and urography (see Fig. 1).

Data was evaluated by using Student's unpaired *t*-test or Fisher's exact test whenever it was appropriate. Results were considered of statistical significance when  $P < 0.05$ . Data are given as medians with ranges in brackets.

## Results

In the 5-year period between January 2002 and December 2006, we performed the donor work-up according to the sequence shown in Fig. 2. The subjects were found unsuited for donation in the specific order presented in Fig. 2.

Overall, there was no significant difference in demographic data between the two groups, as shown in Table 1.

There was however a significantly greater use of cigarettes in the group who were rejected for organ donation when compared with the donor group (Table 1). Among the subjects unsuited for kidney donation, systolic blood pressure was significantly higher when compared with the group who were approved for organ donation (mmHg) 135 (100–220) vs. 130 (100–168),  $P = 0.02$ ; no differences were found with respect to diastolic blood pressure (mmHg) 83 (45–130) vs. 80 (55–100),  $P = 0.10$ .

As shown in Table 2, there was no significant difference between the groups with respect to time spent on medical work-up, renal function or HLA-mismatch.

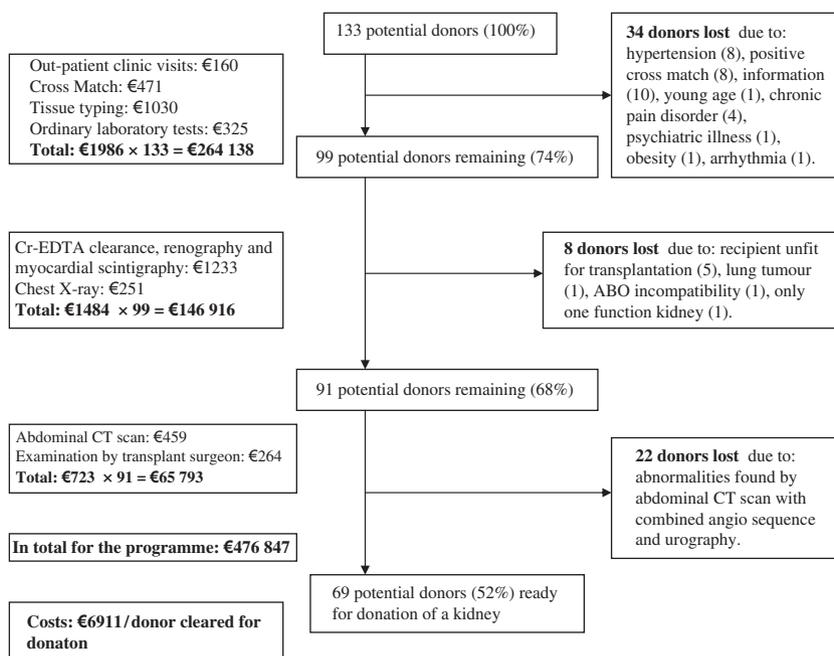
Sixty nine of the 133 subjects were approved for kidney donation and 64 were rejected (48%). Of the 64 rejected

**Table 1.** Demographic data as median (range).

	Donor group	Rejected as donor	Level of significance
Gender (m/f)	33/36	34/30	NS
Age (y)	52 (27–69)	52 (25–67)	NS
Weight (kg)	79 (39–102)	77.4 (41–115)	NS
Height (cm)	172 (142–193)	172 (151–191)	NS
Cigarettes (No.)	0 (0–25)	10 (0–50)	$P = 0.02$
Tobacco users (yes/no)*	27/36	23/21	NS
Alcohol (No.)†	0 (0–4)	0 (0–4)	NS

\*Tobacco user: defined as tobacco used on regular basis during the past year.

†Alcohol is counted in number of drinks/day.



**Figure 2** The reason for exclusion of potential organ donors in the period from January 2002 to December 2006. The cost in euro for the clinical and paraclinical examination during every step of the donor evaluation; an estimate of the cost for 5 years donor work-up in our clinic (in total for the programme). The cost in euro for a single donor (costs). Out-patient clinic visit: general information and clinical examination, BP, ECG; Ordinary laboratory tests analysis: general blood screen with serology and urine screening. Abdominal CT-scan: abdominal CT-scan with combined angio sequence and urography. Examination by transplant surgeon: information about the surgical procedure and clinical examination.

**Table 2.** Medical data as median (range).

	Donor group	Rejected as donor	Level of significance
Systolic blood pressure (mmHg)	130 (100–168)	135 (100–220)	$P = 0.02$
Diastolic blood pressure (mmHg)	80 (55–100)	83 (45–130)	NS
51-Cr-EDTA cl. (ml/min./1.73m <sup>2</sup> )*	98.5 (71–154)	91.5 (66–134)	NS
HLA-mismatch†	3 (0–6)	2 (0–5)	NS
Time spent on medical work-up (month)‡	4 (1–24)	3 (0–48)	NS
Time spent waiting for donation (month)§	3 (0–9)		

\*51-Chrome EDTA clearance normalized for surface area (51-Cr-EDTA cl.).

†HLA, Human Leukocyte Antigen.

‡Time spent on medical work-up: time from first contact to the department for transplantation until either rejection or approval for renal donation.

§Time spent waiting on donation: time from approval as organ donor until surgery.

subjects, 10 dropped out after receiving the general information regarding living kidney donation. Eight had a positive cross-match and eight were excluded because of hypertension.

The abdominal CT-scan including angiography and urography ruled out another 22 (34%) (Table 3). The

**Table 3.** The major abnormalities found by abdominal CT-scan with combined angio sequence and urography.

Reason for finding the subject unsuited as donor	Number of subjects
Difficult vascular anatomy*	14
Possible malignant renal or liver tumour†	6
Kidney stones‡	2

\*Severe arteriosclerosis of the renal vessels or the abdominal aorta; two or more renal arteries/veins that makes donor nephrectomy potentially hazardous; fibromuscular dysplasia.

†Incidental finding of a tumour in the liver (1) kidney (4) or urothelia (1).

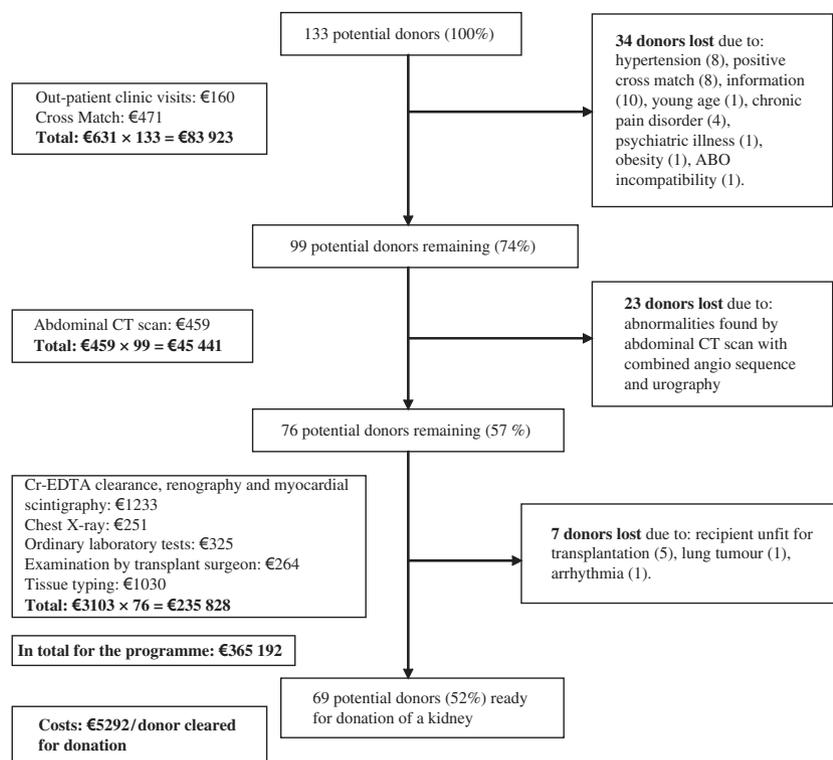
‡One or more kidney stones found by the abdominal CT-scan with urography.

findings were most often vascular abnormalities such as significant polar arteries, stenosis of the renal arteries, fibromuscular dysplasia or severe arteriosclerosis in major arteries such as the aorte abdominal or renal arteries. In six cases, there was suspicion of malignancy in the kidney or liver.

The remaining 16 were excluded for various other reasons as shown in Fig. 2. Chest X-ray revealed one subject with a lung tumour. By renography, we discovered one subject with an asymptomatic single functioning kidney.

One potential donor was found to be ABO incompatible, which at that time made organ donation impossible. The ABO incompatibility was diagnosed early in the

**Figure 3** The proposed new donor work-up programme with a rearrangement of clinical and paraclinical examinations. The cost in euro for the clinical and paraclinical examination during every step of the donor evaluation and an estimate of the cost for 5 years donor work-up is shown. The cost in euro is for a single donor (costs). Out-patient clinic visit: general information and clinical examination, BP, ECG; Ordinary laboratory tests analysis: general blood screen with serology and urine screening. Abdominal CT-scan: abdominal CT-scan with combined angio sequence and urography. Examination by transplant surgeon: information about the surgical procedure and clinical examination.



work-up process as shown in Fig. 2. One donor was unsuited for donation because of new onset severe bradyarrhythmia occurring late in the work-up process. The subject had had a trivial donor work-up until this episode. The severe bradyarrhythmia was of unknown genesis. Five donors were disqualified because the recipients were unfit for transplantation because of poor general condition or very poor cardiovascular status.

An average donor used a median of 4 months (1–24 months) on clinical and paraclinical examinations until being approved for kidney donation. Then further 3 months (0–9 months) was spent waiting for surgery.

It took a median of 3 months (0–48 months) to reject a subject for living kidney donation (Table 2).

The cost for the examinations included in the work up was €4193, because of the ruling out of 48% of the potential donors the cost for clearing one donor for donation was €6911. (Fig. 2). Our donor work-up programme, in the period from January 2002 to December 2006, had a total cost of €476 847. The cost analysis is shown in Fig. 2. The theoretical rearrangement shown in Fig. 3 could reduce the cost for clearing one donor for donation to €5292. This was mainly attributable to avoiding unnecessary tests. It would mean saving a total of 57 sets of both tissue-typing procedures and ordinary blood samples and 23 sets of the following procedures: 52-Cr-EDTA clearance, renography, myocardial scintigraphic and chest X-rays over the 5-year period. The procedures are thus conducted later on and in fewer subjects according to the proposed donor work-up programme shown in Fig. 3.

## Discussion

This study gives an estimated cost of a donor work-up programme and evaluation of the efficacy of the programme. It locates the steps during the programme where the subjects unsuited for kidney donation are identified. We found that our present donor work-up programme have the greatest selection of subjects unsuited for kidney donation during the first and the final step of the clinical and paraclinical examinations as shown in Fig. 2. We were able to identify 56 out of 64 (88%) of the subjects unsuited for organ donation by combining the initial evaluation at the out-patient clinic followed by the abdominal CT-scan with combined angio sequence and urography.

Ten out of sixty-four (15%) withdrew from the programme after receiving information about being a kidney donor. This is a slightly lower number when compared with that found in other studies [13–15] where withdrawal after receiving information is in a range of 20–35%.

The final examination was an abdominal CT-scan with combined angio sequence and urography. This is an easy and accurate procedure giving very detailed information on vascular, renal and extrarenal anatomy and abnormalities of potential clinical importance as shown by *Strang et al.* [16] and *Maizlin et al.* [17]. This procedure identified 22 subjects with abnormalities that made them unsuited for kidney donation.

We had one subject with a solitary functioning kidney. This was diagnosed by the renography but might as well have been found by our abdominal CT-scan with combined angio sequence and urography if it had been done early in our programme.

By applying the abdominal CT-scan with combined angio sequence and urography as one of the first examinations we might risk exposing a greater number of subjects to potentially harmful ionizing radiation. These subjects might have been spared in another set up. According to our calculations we conducted the abdominal CT-scan with combined angio sequence and urography on 91 subjects (Fig. 2) versus a potential number of 99 subjects (Fig. 3). Thus we exposed an extra eight subjects during a 5-year period to ionizing radiation given by the abdominal CT-scan. This should be seen in the context of the eight subjects being spared the time waiting for- and being exposed to- other unnecessary examinations.

One could argue that renal ultrasound including vascular examination with Doppler would be an alternative to the abdominal CT-scan with combined angio sequence. The urography still would be needed to rule out stones and urothelial tumours, which otherwise potentially could have been missed by the ultrasound. In many cases, an angiography would be needed to visualize the renal vessels and the abdominal aorta to ensure that the decision about donor nephrectomy is made on as optimal conditions as possible. The abdominal CT-scan with combined angio sequence and urography gave the transplant surgeon and nephrologist the information that is needed to evaluate renal anatomy and detect pathological conditions that may have influence on kidney donation.

In our study, we identified one subject with urothelial tumour and two with stones (Table 3). From our point of view, it thus seems rational to perform the abdominal CT-scan with combined angio sequence and urography instead of using other methods.

The subjects who volunteered for the donor work-up programme were self-reported as healthy and without serious medical or mental conditions and 69 out of a total of 133 (52%) subjects were found suited to participate in kidney donation. Others have reported a substantially lower success rate; where only 20 out of 117 potential kidney donors were approved for donation and

went through to actually donate a kidney [18]. Our living donor programme thus has a relative high yield. One possible explanation could be that some selection had already taken place at the local departments of nephrology referring some of the potential donors to our clinic.

As per a study by Fehrman-Ekholm *et al.* [15] the three major reasons for not accepting subjects for kidney donation were as follows: 34% were rejected because of immunological reasons, 26% were unsuited because of hypertension or renal disease and finally 20% were not willing to donate after receiving information about the procedure.

In our study, we only found nine out of 133 subjects (7%) who were rejected because of immunological reasons and additional nine subjects (7%) rejected because of hypertension and renal disease. We found ten subjects out of 133 (8%) who were unwilling to proceed to organ donation after receiving general information about the procedure. The differences seen between our study and the study by Fehrman-Ekholm *et al.* [15] may be because of acquired knowledge in the field within the past 12 years namely that the procedure concerning live kidney donation is safe and provides good long-term results for the recipient as well as for the donor [6,7]. Furthermore, it could be speculated that demands for the potential kidney donors are less strict than they have been in the past thus allowing more subjects to proceed to donation.

It has been shown that the time waiting while finishing the work-up programme is considered stressful for the potential kidney donors [19]. So one should try to conduct the donor work-up programme within a reasonable amount of time and make the sequence of examinations well coordinated to satisfy the subjects involved in the programme [19]. Our donor work-up took an average of 3–4 months for a subject to be approved or rejected as a kidney donor. This was mainly because of waiting time for the different investigations conducted in other departments and time waiting for evaluation of test results. The 3 months of waiting for surgery was primarily attributable to lack of surgical capacity but the mutual convenience of the donor and recipient was also an issue because the surgery needed to fit in with other more personal matters such as work-, holiday- and family plans.

The cost of running our donor work-up programme is estimated to be in the range of €476 847 for a 5-year period. The procedures included in the donor work-up reflect a consensus between local practice and international guidelines. Psychological work up was not included in the programme at our clinic but is used in other clinics. If it was applied in our donor work-up an additional €160 for a psychological evaluation should be added per donor cleared for donation. The evaluation should be

placed in the final part of the programme to make it as cost-effective as possible.

The donor work-up programme could be rearranged, as shown in Fig. 3. If all subjects who volunteered for the programme were approved for donating a kidney the estimated cost for one subject to complete the whole donor work-up programme would be €4193. This would hardly be realistic. In theory, it might be possible to lower the costs by 23% to €5292 per donor cleared for donation from the actual cost of €6911 per donor cleared for donation. The donor work-up programme thereby becomes more cost-effective by reducing the use of examinations which are low-yielding and time-consuming. This could be done without compromising the thoroughness of the donor work-up as shown in Fig. 3. The effect of such a change in the order of examinations needs to be proven in practice but the knowledge is important because the donor work-up done in a transplanting centre is very laborious and often low-yielding, as illustrated by Saunders [8].

In conclusion, we have shown that approximately 50% of volunteers for living kidney donation were found to be unsuited for donation. Abdominal CT-scan with angiography and urography was shown to be the procedure that identified the most subjects being unsuited for donating a kidney.

Our retrospective study illustrates the importance of conducting the simple and low-cost clinical and paraclinical examinations (blood-pressure, information and physical examination) early in the donor work-up programme and combining it with a high yielding procedure – illustrated in Fig. 3 – to make the donor work-up more cost-effective and less time-consuming.

## Authorship

JL: collected data and wrote paper. SSS, BF-R: designed study and evaluated data.

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