



Ethical Issues in the Use of Suboptimal Kidneys for Transplants: An Italian Point of View

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ABSTRACT

The shortage of organs leads to the need for utilizing suboptimal kidneys for transplantation. The distinction between optimal, marginal, and suboptimal kidneys leads surgeons to face not only technical problems but also ethical and legal issues related to clinical advantages offered by the transplant of a nonstandard kidney and the acquisition of consent. Between 1999 and 2015, we performed 658 transplants, 49 (7.5%) using suboptimal kidneys. All patients were alive and with vital graft throughout follow-up. We did not encounter any major surgical complications. From a technical point of view, our experience and literature review confirm that transplant of suboptimal kidney leads to good clinical results but exposes patients to a increased risks of surgical complications. Therefore, these interventions must take place in hospitals fully prepared for this type of surgery and performed by experienced transplant surgeons with proper matching between organ and recipient. Considering the insufficient resources available, from an ethical and legal point of view, doctors play an essential role in optimizing the use of these kidneys by avoiding wastage of organs, ensuring that transplants are done in suitable patients, and that patients are fully informed and aware of the risks and benefits associated with the specific suboptimal kidney being transplanted. We believe that, in highly specialized centers, the number of suboptimal kidney transplants should be increased, as their use has shown good clinical results and carries fewer ethical issues compared with marginal kidneys. Further, suboptimal kidneys may also be proposed for use in young patients with end-stage renal disease.

SINCE the first kidney transplant took place in 1954, enormous progress has been made in surgical outcomes and immunosuppressive therapy. Thus, kidney transplantation has become the most effective treatment for end-stage renal disease (ESRD).

In Italy, as of December 31, 2015, there were 9070 patients on the waiting list for all organ transplants and, of these, 6765 patients were awaiting kidney transplantation (76%). As of January 1, 2015, 6906 patients were on the kidney transplant waiting list, and throughout the year a further 1897 patients were added, totaling 8803 patients. There were 2038 patients removed from the waiting list, but only 1576 of these were because they actually received a kidney transplant. The others were removed because they either died or presented with clinical changes

contraindicating transplantation. The mean waiting period for a kidney transplant was 2.4 years, with a mortality rate of 1.6% [1].

The data just presented show that the number of kidneys available in Italy has not satisfied the need for organs and, therefore, throughout the year, the number of patients on the kidney transplant waiting list has remained stable. The situation has been similar worldwide.

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Italian legislation regarding cadaveric organ donation permits the harvesting of organs only from patients who, during their lifetime, expressed their intention to donate organs or, in cases of unexpressed denial, if the patient's relatives express consent to donation. This led to a shortage of organ donations. Therefore, to expand the donor pool, it has become necessary to utilize marginal donor organs.

Generally, a kidney is considered marginal when harvested from a donor >60 years old, or those between 50 and 59 years with 2 of the following characteristics: cerebrovascular accident as cause of death, hypertension, serum creatinine >1.5 mg/dL, and, more generically, a kidney with qualitatively reduced working parenchyma [2,3].

As ethical and legal issues related to nonstandard kidneys have been considered and dealt with, the utilization of marginal kidneys is now accepted for certain patients, particularly elderly patients [4,5].

There is a subcategory of marginal kidneys, called suboptimal kidneys, with intermediate features between standard and marginal kidneys. Suboptimal kidneys are organs that, although harvested from a standard donor, present complex arterial anomalies (>2 arteries, although with a single patch or separated so as to require a double anastomosis or bench reconstruction); parenchymal damage, such as focal sclerosis areas or sutured polar branches accidentally damaged during organ harvest; or complex anomalies of the excretory tract (complete double district), which can lead to a quantitatively but not qualitatively reduced nephron mass [6].

The lack of organ donation and the benefits transplantation can provide to patients in ESRD are the main reasons why suboptimal kidneys have come into use. Our

goal in this study was to highlight some of the ethical problems related to use or nonuse of suboptimal kidneys for transplant.

MATERIALS AND METHODS

Between January 1999 and December 2015, 658 kidney transplants from cadaveric donors were performed in our transplant unit, with 49 (7.5%) of these being suboptimal organs.

Patients transplanted with a suboptimal kidney, in addition to being on the standard waiting list, were placed on a waiting list dedicated only to patients who gave consent to receive a suboptimal kidney. These patients were fully informed regarding the risks associated with suboptimal kidney utilization. This information was provided at the time of enrollment onto the waiting list and reviewed on the day of transplant. On both occasions, patients signed a specific consent document.

Of the 49 suboptimal kidneys, 3 had 4 arteries, 8 had 3 arteries on a single patch, 17 had 2 separate arteries with small separate patches sequentially anastomosed, 9 had a transected polar branch reconstructed on a single aortic patch together with the main artery, 4 had a polar branch tied, and 8 had a complete urinary double district (Table 1 and Fig 1).

RESULTS

All suboptimal kidneys transplanted in our transplant unit showed good renal function with creatinine levels ranging from 0.8 to 2.5 mg/dL, reached within 20 days. All patients were alive and with a vital graft during the follow-up period (range, 24–60 months). We had no major complications (Table 2) and patients were satisfied with the clinical results. After transplant, none of our patients complained about incorrect or incomplete information on consent and neither

Table 1. Characteristics of Donors and Recipients

	Donors	Recipients*
Anatomic abnormality	Kidneys with: (a) 4 arteries: 3 pts (b) 3 arteries on single patch: 8 pts (c) 2 arteries on separate patch: 17 pts (d) Reconstructed transected polar branch: 9 pts (e) Tied polar branch: 4 pts (f) Complete urinary double district: 8 pts	—
Cause of death	Trauma 9 pts	—
	Cerebrovascular accidents 40 pts	—
Female	15 pts (1a+3b+5c+2d+1e+3f)	38 pts (2a+6b+14c+8d+3e+5f)
Male	34 pts (2a+5b+12c+7d+3e+5f)	11 pts (1a+2b+3c+1d+1e+3f)
Age ≤40 y	10 pts (2a+1b+5c+1d+1f)	9 pts (6c+1d+2f)
Age 41–55 y	33 pts (1a+6b+10c+7d+3e+6f)	29 pts (3a+7b+4c+7d+3e+5f)
Age ≥56 y	6 pts (1b+2c+1d+1e+1f)	11 pts (1b+7c+1d+1e+1f)
eGFR ≤50	—	36 pts (3a+7b+10c+9d+4e+3f)
eGFR 51–80	18 pts (2a+6b+6c+1d+1e+2f)	13 pts (1b+7c+5f)
eGFR >80	31 pts (1a+2b+11c+8d+3e+6f)	/
Diabetes	—	4 pts
Hypertension	15 pts	39 pts
BMI >31	14 pts	/

Abbreviations: BMI, body mass index; eGFR, estimated glomerular filtration rate; pt, patient; y, year.

*Three-year follow-up. No recipient had anatomic abnormalities or major comorbidities other than diabetes and hypertension.

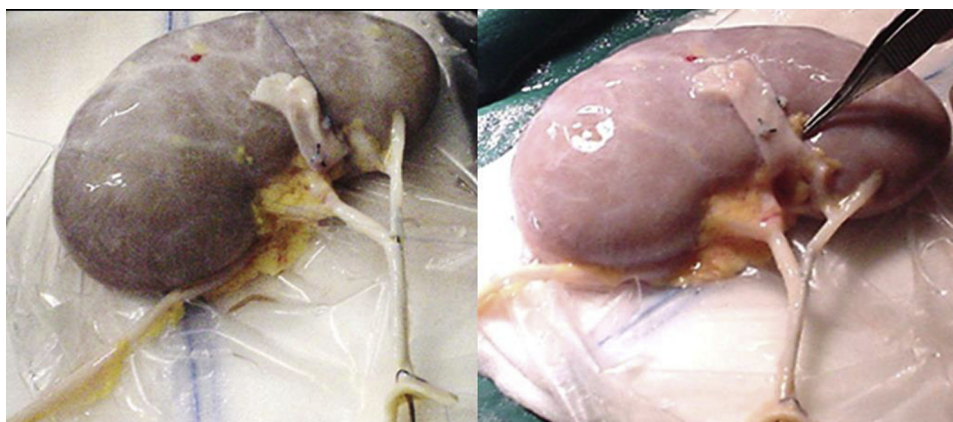


Fig 1. Reconstruction of a polar branch.

our group nor transplant unit was targeted for any legal action from patients.

Ethical Considerations

It may seem evident and fair that all patients in ESRD should receive optimal kidneys, but unfortunately this is not possible. Thus, the lack of available donors makes use of suboptimal kidneys necessary.

Transplant of a suboptimal kidney—a kidney with a quantitatively but not qualitatively reduced amount of working parenchyma—presents more technical difficulties than a standard organ transplant and exposes the patient to a higher risk of surgical complications [7–11]. Use of suboptimal kidneys may be associated with a higher risk of graft loss and morbidity and mortality of patients, so their use requires experienced surgeons [12–16].

Justification for the utilization of suboptimal kidneys comes from the fact that, even if not ideal, it offers the ESRD patient a better quality of life and longer survival than dialysis. To not make use of suboptimal kidneys may also potentially affect the chances of many patients to ever receive a transplant [17].

It may seem ethically questionable to transplant a suboptimal organ that may lead to the need for graft nephrectomy and return of the patient to the waiting list, with enhanced technical difficulties in a further transplant along with immunologic sensitization; however, suboptimal organ utilization can be considered a better alternative to dialysis or death while waiting for a transplant [18–21]. We must

also consider that even a transplant with an optimal kidney could result in early loss of the graft, so not using a suboptimal kidney could imply condemning a patient to death while waiting for the perfect organ that may never materialize; indeed, even if the ideal organ does become available, there is no guarantee the transplant would succeed. Further, using a suboptimal kidney does not necessarily mean there would be early graft loss [22].

Consent plays a very important role in the process leading up to transplant of a suboptimal kidney. For consent to be considered valid, it is necessary to provide the patient with full, comprehensive, accurate information relating to receiving a suboptimal kidney, including all benefits and risks. If any information provided were found to be insufficient, falsified, or omitted, consent would be deemed vitiated and invalid [23,24].

Negligent information before consent may also lead to civil and penal action against the surgeon. If not correctly informed, the recipient could claim indemnity for damages in the case of earlier loss of the graft, as compared with prediction of the organ's survival for optimal kidney transplant [25,26].

The recipient must be sufficiently informed about the transplant of a suboptimal kidney and all implications of graft survival so that an informed, autonomous decision can be made whether to accept or refuse the procedure. The doctors involved are forbidden to omit information relating to suboptimal kidney utilization even when they consider this to be in the interest of the patient and that it may result in the possibility of the recipient refusal [27,28].

Table 2. Complications Occurred in Our Transplant Unit

Number of Kidneys	Complications
3 kidneys with 2 arteries of similar gauge with small separate patches	Showed a thrombosis of the smaller branch that caused a localized infarct that did not affect the early functional recovery
1 kidney with a complete double district	Presented leakage on postoperative day 7, treated with a conservative therapy
4 kidneys with polar branch accidentally tied	Manifested an ischemic zone during the reperfusion that did not affect the functional recovery
1 kidney with 4 arteries	Showed a thrombosis of 2 of the 4 branches at 6 months posttransplant

The unpredictability of when an organ will become available is the reason why a potential recipient should be informed on the opportunity to receive a suboptimal kidney when placed on the waiting list, so as to provide the opportunity to express in advance the will to accept or refuse the organ [29]. This question should be asked again to the recipient, even at the time the transplant, highlighting the specific characteristics that make that specific kidney a suboptimal organ and the particular additional risks linked to that organ. So, the patient has the right to change his/her decision at any point up until the surgery takes place.

In our experience, the respect of all the points previously listed and the sign of the consent occurred in the way explained above, lead: on the ethical side, to the utilization of suboptimal kidneys only in correctly informed patients and conscious of the benefit and risks related to the utilization of those organs; on the legal side, to the absence of legal claims. We did not incur in any legal action as the suboptimal kidney transplants we performed showed good clinical results, so there was no animosity from the patients. We emphasize that the steps taken and procedures we used help to protect us in the event of legal actions.

It is important as to how selection of ESRD patients is conducted among those who are candidates for receiving a suboptimal kidney. In contrast to marginal kidneys, which are usually transplanted in elderly recipients, suboptimal kidneys may also be advantageous in young patients, although this requires consideration of factors such as weight, vascular and excretory tract conditions, and the specifics of the suboptimal organ [30–33]. Kidneys with quantitatively reduced nephron mass have shown better results when transplanted in a recipient of smaller size than the donor, preferably women [6,34].

One socioeconomic aspect that should also be considered is how utilization of suboptimal kidneys offers certain economic advantages, whereas missed utilization of an organ already obtained during multiorgan harvesting is a waste of economic resources within the national health system. That is, in cases where the organ has ultimately not been used for transplant, the economic resources used could have been allocated elsewhere.

CONCLUSIONS

The utilization of suboptimal kidneys is still a controversial subject. On the one hand, use of such organs seems to go against the right of the patient to receive the best treatment available; on the other hand, the lack of donors and evidence of benefits of transplantation, even with suboptimal kidneys, on a patient's quality of life and its superiority to dialysis, justify the use of such organs.

The ethical problems related to the use of suboptimal kidneys will not be resolved until the time when optimal kidneys are available for every patient in ESRD; however, this is very unlikely, especially until law regarding donation in our country will leave it to the altruistic consent of the donor or of his/her relatives. So, in this setting of lack of

available organs, all resources should be used, including suboptimal kidneys, leaving autonomy to the potential recipient whether to accept or refuse the donation.

For successful transplantation of a suboptimal kidney it is necessary to establish a proper match between organ and recipient. Patient selection plays a fundamental role: the recipient must be of lower weight and have less muscle mass than the donor, so as to be adequate for the kidney's working parenchyma transplanted. Those characteristics are generally identified in female recipient. The transplant of a suboptimal kidney offers more technical difficulties than a standard organ transplant and exposes the patient to a higher risk of surgical complications, so the transplant must take place in hospitals fully prepared for this type of surgery and must be performed by experienced transplant surgeons. Only in this way can the surgical risk related to the utilization of suboptimal kidneys be acceptable.

The distinction between optimal and suboptimal kidneys can lead to legal issues, such as the civil responsibility related to incomplete information from doctor to patient. A correct acquisition of consent is fundamental to decrease the risks of legal actions. Doctors must provide complete and honest information about the risks related to use of suboptimal kidneys to allow the patients to evaluate the risks and benefits of transplant of such organs and to take their decision in complete autonomy and freedom. Negligent information before consent may lead to civil and penal action against the surgeon.

Under such circumstances doctors play an essential role by providing correct and complete information to the recipient about the risks and benefits related to receiving the specific suboptimal kidney in relation to the recipient's clinical condition. The patient, once correctly informed, can then make an autonomous decision as to whether to accept or refuse donation.

We believe that the use of suboptimal kidneys should be expanded because it has shown good clinical results and carries fewer potential ethical issues than use of marginal kidneys. In our view, this could also be an option for young patients affected by ESRD.

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