

What can be Proposed to Stop Forced Organ Harvesting and Transplant Abuse in China?



Yoshihide Ogawa* and Yuho Kono

Department of Urology, Towa Hospital, Japan

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*Corresponding author: Yoshihide Ogawa, Department of Urology, Towa Hospital, Japan

Summary

To eradicate organ trafficking and transplant tourism, the Declaration of Istanbul seems to solely depend on maximizing deceased donation. However, utilizing therapeutic kidneys that are destined to be discarded may help to suppress the rise of organ trafficking and transplant tourism. The China Organ Transplant Response System appears to be well-developed and advantageously positioned because therapeutic kidneys referred from urologists can be easily restored, transferred and transplanted to well-matched HLA recipients. Such practices could be helpful in increasing the number of donor kidneys in China without sacrificing prisoners of conscience.

Abbreviations: DoI: Declaration of Istanbul; HLA: human leukocyte antigen; DICG: Declaration of Istanbul Custodian Group; AML: Angiomyolipoma; RCC: Renal Cell Carcinoma; PN: Partial Nephrectomy; AUA: American Urological Association; EAU: European Association of Urology; RN: Radical Nephrectomy

Introduction

In response to growing concerns about international organ trafficking and transplant tourism, the Declaration of Istanbul (DoI) was derived from the consensus reached at the summit meeting convened by the Transplantation Society (TTS) and the International Society of Nephrology (ISN) in 2008 [1]. The aim was to provide guidelines to combat transplant commercialism using poor people as a source of organs for the rich. To implement the declaration, a custodian group (DICG) was created to follow up on progress in fulfilling the DoI aims. There is no doubt that the DoI has exerted an impact on organ trafficking and transplant tourism around the world [2]. To celebrate the 10th Anniversary of the DoI, during the International Congress of TTS in Madrid in 2018, the DICG carried out a comprehensive consultation to update the DoI in response to clinical, legal and social developments in the field [3,4]. Despite disparate extensive efforts made by the DICG, the DoI has not been able to address the root of the problem, which is basically organ shortage, and transplant tourism and commercialism are still common in many hot spots [2]. It appears that maximizing deceased donation is the last resort for achieving the aim of the DoI [2].

According to the China Tribunal's conclusion and judgment in London in June 2019, forced organ harvesting has been extensively practiced for years in China, and prisoners of conscience (Falun Gong practitioners in detention camps and

the Uyghurs in internment (re-education) camps) have been the main sources of organ supply. Mass forced organ harvesting from prisoners of conscience in China over the years constitutes a crime against humanity under international law, an informal, independent "people's tribunal" has concluded. Broad-scale medical testing and on-demand persecution of these groups have been committed for transplantation over a long period of time, and systematic state-sanctioned forced organ harvesting continues today [5]. In response, the International Coalition to End Transplant Abuse in China (ETAC), the pressure group that convened the tribunal, called for doctors and organizations worldwide to stop all collaboration related to transplantation with China [5].

However, Huang Jiefu (head of the China National Organ Donation and Transplantation Committee and chairman of the China Organ Transplantation Development Foundation) claims that US law and regulation states that 5% of organ donations of any particular organ type can be given to foreigners for transplantation (the 5 percent rule). That is, the US uses this law to violate the global regulation of "self-sufficiency" in the transplant field [6]. Of course, given global opposition, they are also revising it (non-US citizens/non-US residents are further divided into those traveling to the US for reasons other than transplant and those traveling to the US for transplant) [7]. In 2016, the US performed 280 organ transplants for foreigners, far

beyond the 5% limit [8,9]. According to some advocates active in donor transplant, foreign nationals jetting to the US solely to shell out cash for organ transplants is a growing problem [10]. Apart from this issue, many organs in the US do not come from voluntary citizen donations: some groups, for instance poor people and refugees, will, for their livelihood, come to the US and sell their organs. Therefore, the US has the most rampant organ trafficking in the world [6]. Furthermore, the Chinese authority insists that stories about forced organ harvesting in China are imaginary and baseless, lacking any factual foundations (Chinese Foreign Ministry spokesperson, Hua Chunying, 2016) [11].

Japan's strict transplantation laws and innate cultural beliefs have kept its organ donation rates low. The current shortage of available deceased organs leads to a high mortality rate among patients on the waiting list for a kidney transplant. The slow progress on brain-dead organ donation in Japan, the donor shortage crisis and weariness from waiting prompt dialysis-intolerant patients to travel overseas to seek transplantation and donor kidneys in foreign countries [12-14]; Japan has faced international criticism over this issue for many years [14]. A survey conducted by the Japanese Health Ministry in 2006 confirmed that at least 522 Japanese patients (heart 103, liver 221, and kidney 198 cases) had undergone transplants abroad from 1984 to 2005, with the true number being much higher [15]. There has been little change since that time. Popular destinations for Japanese transplant tourism include the US, Asia and, disputably, China. In reality, dialysis patients seeking transplant abroad will incur a high cost (approximately \$200,000), and the Japanese Ministry of Health, Labor and Welfare recently issued a notice to cover part of the expenses shouldered by patients traveling abroad to undergo organ transplants who are in need of urgent surgery [16].

To compensate for the donor shortage, clinical transplantation utilizing therapeutic kidneys was empirically practiced without any ethical conflict until 2007 in Japan [17]. An organ trafficking problem connected with the use of therapeutic kidneys forced the Japanese government (Ministry of Health, Labor, and Welfare) to issue an official notice in 2007 to ban kidney transplantation using donors with therapeutic kidneys. After learning that a large number of usable therapeutic kidneys (e.g., small renal tumors) were discarded every year [18], the Tokushukai Medical Group launched a restored kidney transplantation team to address the problem of saving "unrescuable" dialysis patients who were eager to undergo transplantation but did not have a suitable donor because of the limited supply for traditional kidney transplantation. Additional official notification subsequently issued from the Ministry of Health, Labor and Welfare announced that there is no limit on using any kind of therapeutic kidney for restored kidney transplantation for cases in clinical trials only. This notification motivated initiation of a clinical trial of restored kidney transplantation (2008) [19]. The transplantation of nephrectomized, restored kidney with small renal cell carcinoma (RCC) has been sporadically reported previously, and its frequency has gradually increased. Yu et al.

summarized 97 cases [20], including 8 and 10 Japanese cases described in articles [21,22]. Based on the relevant literature review [20,23,24], a trial of living renal transplantation using restored therapeutic kidneys (kidney tumor, kidney stone, ureteral tumor, ureteral stricture, and cystic kidney) between family members [25] and another trial of living renal transplantation with restored kidneys between third parties were designed in 2009 [22]. These two pilot studies of the Tokushukai Medical Group started as open interventional trials with an estimated enrollment of five cases each.

Despite their original aim of eradicating transplant tourism, Japanese academic reactions to restored kidney transplantation using therapeutic kidneys were unusually negative, and five Japanese academic associations (Transplantation, Urology, Dialysis Therapy, Nephrology, and Clinical Renal Transplant) issued a "statement against restored allograft transplantation using therapeutic kidneys", insisting that there had not been any clinical experience of restored kidney transplantation worldwide. The donor kidney had to be healthy (the use of therapeutic kidneys, including renal aneurysm, AML, nephrosis, etc., and that of kidneys with renal tumors and ureter tumors was not medically valid, as *ex vivo* surgery or autografting was the standard treatment in Japan) [25].

The lessons learned from the living-related kidney transplant trial using therapeutic kidneys included a limited number of incidental cases, some of which were ABO-incompatible and high in HLA-mismatch, but almost no ethical problems in making decisions of whether to donate to their relatives [25]. The living unrelated transplant trial between third parties met difficulty in recruiting donor kidneys despite many nephrectomized kidneys for small RCC being discarded and needed some network organization for kidney procurement/allocation and a recipient registry to select well-matched HLA recipients [22]; therefore, Western Australian nation-controlled systematic program may be ideal [26].

The clinical trials of restored kidney transplantation using nephrectomized kidneys with small renal tumors (tumor size < 4 cm) were slow and steady in their progression (Tokushukai Medical Group). Ultimately, they performed 18 cases of restored kidney transplantation over 7 years to save "unrescuable" dialysis patients, and 10 recipients are still surviving with functional grafts and without tumor recurrence [25]. They intended to expand the procedure into general practice. After several years, their proposed trial has been approved for Advanced Medical Treatment regulated under the Medical Care Law to perform restored kidney transplantation using small RCC (tumor size < 7 cm) at any certified hospital in Japan. This trial, requiring the collection of 42 cases to obtain good evidence to verify the utility and safety of the procedure, was approved in February 2019. The project may provide novel options for living unrelated kidney transplantation between third parties but is now pending to financial limitations and a shortage of capable staff in the Tokushukai Medical Group.

Widespread therapeutic kidney donation could be expected to help relieve the donor shortage. More than 80% of small renal tumors (<4 cm) are treated by nephrectomy in Japan, so it is estimated that 2,000 kidneys with small RCCs are nephrectomized and discarded every year [18]. The Japanese Ministry of Health, Labor and Welfare conducted a questionnaire survey of treatment for a small RCC in 2012; 1082 patients with a small tumor underwent nephrectomy, while 1235 patients underwent partial nephrectomy (PN) in major teaching hospitals and cancer centers [25]. Despite guidelines in the US and Europe stating that a PN is the standard of care for a patient with a T1 renal mass, the application of PN for treating small renal masses varies widely. The definition of the technical feasibility of a PN and the adherence to AUA and EAU guidelines were influenced by renal tumor case volume, PN% volume and practice setting [27]. More than 3,000 kidneys with tumors go untransplanted and are discarded in the United States each year [28,29]. The kidneys that are removed are discarded, and their use may provoke fewer ethical issues than the use of kidneys from healthy living donors. The rapid adoption of robotics has introduced a paradigm shift, but this change has not been dramatic for the treatment of RCC. For the treatment of localized RCC, the use of PN has increased and surpassed radical nephrectomy (RN). Robot-assisted laparoscopic PN has rapidly become the most common surgical modality [30]. The rate of PN increased in younger patients, while RN remained stable. An increase in overall surgical treatment was observed, mainly due to increased treatment of elderly patients [31]. RN still seems to be a mainstay for 4 cm to 7 cm RCC according to a recent systematic review and meta-analysis [32]. The great concept “Mottainai” by Prof. Wangari Maathai denotes the state of having sympathy and gratitude for world peace through environmental conservation and not wasting resources; the 3Rs (“reduce, reuse, and recycle”) should also be invoked here to solve the organ shortage crisis by utilizing kidneys with small renal tumors for transplantation. Utilizing these previously discarded kidneys may help to suppress the rise of organ trafficking and transplant tourism [19].

The WHO and UNOS accept therapeutic kidney donations, including donations of kidneys with small renal tumors [17]. Wide acceptance of therapeutic kidney donation might result in some changes/improvements to reduce transplant tourism and relieve the donor shortage. The Western Australia Kidney Transplant Service has established a program of kidney transplantation using therapeutic kidneys, including small renal tumors and ureteric injuries [26]. This type of program may expand the pool and be an additional donor resource.

In conclusion, Chinese urologists should be encouraged to refer a kidney to transplantation service when considering a radical nephrectomy for a small kidney tumor. There are many potential donors (Falun Gong practitioners in detention camps and the Uyghurs in internment camps), some of whom have

therapeutic kidney diseases and may require nephrectomy, avoiding many ethical problems. The China Organ Transplant Response System is well-developed and advantageously positioned because these therapeutic kidneys can be easily restored, transferred and transplanted to well-matched HLA recipients. These practices can clearly help to increase the number of donor kidneys without sacrificing prisoners of conscience.

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