

Brief Communication

The Impact of the Israeli Transplantation Law on the Socio-Demographic Profile of Living Kidney Donors

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The Israeli transplantation law of 2008 stipulated that organ trading is a criminal offense, and banned the reimbursement of such transplants by insurance companies, thus decreasing dramatically transplant tourism from Israel. We evaluated the law's impact on the number and the socio-demographic features of 575 consecutive living donors, transplanted in the largest Israeli transplantation center, spanning 5 years prior to 5 years after the law's implementation. Living kidney donations increased from 3.5 ± 1.5 donations per month in the pre-law period to 6.1 ± 2.4 per month post-law ($p < 0.001$). This was mainly due to a rise in intra-familial donations from 2.1 ± 1.1 per month to 4.6 ± 2.1 per month ($p < 0.001$). In unrelated donors we found a significant change in their socio-demographic characteristics: mean age increased from 35.4 ± 7.4 to 39.9 ± 10.2 ($p = 0.001$), an increase in the proportion of donors with college level or higher education (31.0% to 63.1%; $p < 0.001$) and donors with white collar occupations (33.3% to 48.3%, $p = 0.023$). In conclusion, the Israeli legislation that prohibited transplant tourism and organ trading in accordance with Istanbul Declaration, was associated with an increase in local transplantation activity, mainly from related living kidney donors, and a change in the profile of unrelated donors into an older, higher educated, white collar population.

Received 02 June 2014, revised 26 October 2014 and accepted for publication 29 October 2014

Background

The enormous demand for kidney transplantations and the worldwide shortage of organs for transplantation is a stimulus for black market living donor organ sale, either locally or through transplant tourism (1,2). The challenge of verifying altruism and ruling out exploitation is a key element in transplant policy throughout the world (3,4).

As of 1997, living organ donations in Israel are regulated by administrative guidelines (5,6). These require all potential donors to be subjected to psychosocial evaluation and to be approved by a committee appointed by the national transplantation center to ascertain their free will to donate and an altruistic motive. These administrative guidelines, along with low deceased donation rates in Israel (7), motivated patients to seek transplantation from paid donors outside Israel. These paid donors were mainly non-Israelis, located by middle-men at the transplant venue, but also some Israelis who failed to pass the scrutiny of the National Transplantation Center committee, and circumvented Israeli regulations by travelling with their recipient abroad and having the procedures done there (8). These transplantations were easily accessible as they were arranged by middlemen and reimbursed by private and national insurance companies. In 2006, the Israeli ministry of health instructed medical insurers not to reimburse patients for transplants from living donors done outside Israel, unless organ trading was ruled out (9). These directives, however, had no formal power and very little effect (10). In 2008, on top of the above-mentioned restrictions, the Israeli parliament passed the transplantation law.

This law decrees that any involvement of a third party in organ trading is a criminal offense, punishable with up to three years of imprisonment (11,12). The law clearly bans the reimbursement of organ transplantation anywhere outside of Israel if the procurement of the organ and its transplantation have been performed contrary to the law of that country and if the stipulations of the Israeli law regarding organ trade are contravened. The Israeli transplantation law was passed in the same year and stands in accordance with the Istanbul declaration on organ trafficking and transplant tourism and conforms to similar measures taken by other national governments in their combat against organ trading (1,2,13). The Istanbul declaration was followed by government action and progressive legislation in some of the transplant tourism

“destination” countries. In the Philippines, for example, one of the main venues for Israeli patients, the government implemented regulations that prohibit living donors from the local population to provide organs for transplant to non-Filipinos. Those regulations were followed by a dramatic fall in transplant tourism to this country (8).

These measures dramatically decreased transplant tourism from Israel, creating a supply void that needed to be filled. A recent study from the Israeli transplantation center (7) indeed found a significant decrease in the number of kidney transplants performed abroad with a concomitant increase in both living and deceased local organ donation rate.

In this study, we wish to examine the effect of the new law on the number and the socio-demographic profile of the Israeli living-kidney donors and the interrelations between unrelated donors and recipients as an indication to their motive (14,15) and as an insight to whether this prohibition has transformed organ tourism from Israel into illegal organ sale locally (16).

Materials and Methods

We compiled data on all living kidney donors who were operated at the transplantation department of the Rabin Medical Center (RMC) from January 2004 to December 2013 (n=575). Our study population encompassed 70% of all living kidney donations in that period of time in Israel (n=821) and includes patients from all parts of the country.

We collected data on donors and recipients in two equal time frames: prior to the law from January 2004 to December 2008 and after from January 2009 to December 2013. Socio-demographic data was retrieved with the approval of the Rabin Medical Center bioethical committee (approval of study 0055-10, no. 5878) and included: relationship to the recipient (type of relationship or unrelated), time of transplant, gender, age, marital status, education, and employment. Following the 2008 transplantation law, we labeled as “related” any donor who is a first- or second-degree family member. This included parents, children, siblings, spouses, brothers- and sisters-in-law, uncles, aunts and cousins, grandparents, and grandchildren. Age, marital status, and education were classified into: up to 40 years of age or above, married or single (unmarried, widow, or divorced), high school level education and below or college level and above. Occupation was classified as “white collar” (including professions that require an academic education, managers, self-employed and high-paid service occupations), “blue collar” (including low and medium salaried workers, temporaries, and professions that do not require an academic education and not working (including students, unemployed, or retired).

Transplantation surgery in Israel is fully covered for every resident by the national health insurance and includes both recipient and donor operations and all subsequent follow up.

No change in the evaluation process or exclusion criteria of donors was made during the study period.

Methods of analysis

Data are presented as mean ± standard deviation for continuous variables and frequencies (%) for categorical variables.

For examining changes before and after the law, we used comparative and descriptive analyses. In order to indicate significant changes in the groups before and after the law, we used Chi square tests for categorical variables and t-tests for normally distributed continuous variables or Mann-Whitney U-test for non-normally distributed variables.

The significance of differences between donors and patients were evaluated by ANOVA with repeated measures. The effect of time period was evaluated for the primary outcome. When ANOVA showed a significant donor-patient-by-time interaction, a paired t-test was applied.

For statistical analysis we used SPSS software version 20.

Results

Living kidney donations rose from 211 in the pre-law period (January 2004 to December 2008) to 364 post-law (January 2009 to December 2013) (3.5 ± 1.5 donations per month to 6.1 ± 2.4 per month, p < 0.001). The increased living donation was due to an increase in donations from related donors in the post-law period, from 58.8% of donors pre-law to 76.0% of donors post-law (2.1 ± 1.1 per month to 4.6 ± 2.1 per month; p < 0.001) while unrelated donation rate was not changed (1.5 ± 1.3 per month to 1.5 ± 1.3 per month; p = 1.0). The yearly rates of related and unrelated living donations are presented in figure 1.

Effect on donors’ demographics

Following the enactment of the law, the demographic characteristics of living kidney donors in respect to age, marital status, and education level was significantly changed (Table 1). This difference is mainly due to changes in the unrelated donors’ profile as the related group did not significantly change (Table 1). In the unrelated group, the mean age of donors increased from 35.4 ± 7.4 to 39.9 ± 10.2 (p=0.001), the proportion of donors with college level and above education rose from 31.0% to 63.1% (p < 0.001) and the proportion of donors with white-collar occupations rose from 33.3% to 48.3% (p = 0.023). In the unrelated group we also found an increase in the proportion of married donors, with trend to significance from 52.9% to 67.8% (p = 0.063).

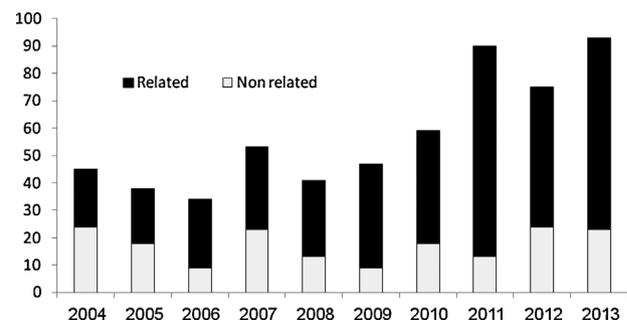


Figure 1: Living kidney donors 2004–2013 by relation to patient.

Table 1: Sociological composition of patient and donors before and after the law

| | Related donors (n = 401) | | | Unrelated donors (n = 174) | | | All donors (575) | | |
|------------------------|--------------------------|---------------|---------|----------------------------|---------------|---------|------------------|---------------|---------|
| | Before the law | After the law | p-value | Before the law | After the law | p-value | Before the law | After the law | p-value |
| Gender | | | | | | | | | |
| Male | 50 (40.3%) | 119 (43.0%) | 0.662 | 71 (81.6%) | 62 (71.3%) | 0.152 | 121 (57.3%) | 181 (49.7%) | 0.084 |
| Female | 74 (59.7%) | 158 (57.0%) | | 16 (18.4%) | 25 (28.7%) | | 90 (42.7%) | 183 (50.3%) | |
| Total | 124 (100.0%) | 277 (100.0%) | | 87 (100.0%) | 87 (100.0%) | | 211 (100.0%) | 364 (100.0%) | |
| Age | | | | | | | | | |
| Up to 40 | 42 (33.9%) | 91 (32.9%) | 0.84 | 63 (72.4%) | 50 (57.5%) | 0.039 | 105 (49.8%) | 141 (38.7%) | 0.010 |
| 41 and above | 82 (66.1%) | 186 (67.1%) | | 24 (27.8%) | 37 (42.5%) | | 106 (50.2%) | 223 (61.3%) | |
| Total | 124 (100.0%) | 277 (100.0%) | | 87 (100.0%) | 87 (100.0%) | | 211 (100.0%) | 364 (100.0%) | |
| Mean Age | 45.1 ± 11.5 | 45.8 ± 10.9 | 0.6 | 35.4 ± 7.4 | 39.9 ± 10.2 | 0.001 | 41.1 ± 11.1 | 44.4 ± 11.0 | 0.001 |
| Marital Status | | | | | | | | | |
| Single | 24 (19.4%) | 51 (18.4%) | 0.890 | 41 (47.1%) | 28 (32.2%) | 0.063 | 65 (30.8%) | 79 (21.7%) | 0.017 |
| Married | 100 (80.6%) | 226 (81.6%) | | 46 (52.9%) | 59 (67.8%) | | 146 (69.2%) | 285 (78.3%) | |
| Total | 124 (100.0%) | 277 (100.0%) | | 87 (100.0%) | 87 (100.0%) | | 211 (100.0%) | 364 (100.0%) | |
| Education | | | | | | | | | |
| College level or above | 39 (34.5%) | 80 (37.2%) | 0.629 | 26 (31.0%) | 53 (63.1%) | <0.001 | 65 (33.0%) | 133 (44.5%) | 0.011 |
| High school or below | 74 (65.5%) | 135 (62.8%) | | 58 (69.0%) | 31 (36.9%) | | 132 (67.0%) | 166 (55.5%) | |
| Total | 113 (100.0%) | 215 (100.0%) | | 84 (100.0%) | 84 (100.0%) | | 197 (100.0%) | 299 (100.0%) | |
| Occupation | | | | | | | | | |
| White collar | 39 (31.5%) | 96 (34.7%) | 0.49 | 29 (33.3%) | 42 (48.3%) | 0.023 | 68 (32.2%) | 138 (37.9%) | 0.31 |
| Blue collar | 50 (40.3%) | 118 (42.6%) | | 49 (56.3%) | 31 (35.6%) | | 99 (46.9%) | 149 (40.9%) | |
| Not working | 35 (28.2%) | 63 (22.7%) | | 9 (10.3%) | 14 (16.1%) | | 44 (20.9%) | 77 (21.1%) | |
| Total | 124 (100.0%) | 277 (100.0%) | | 87 (100.0%) | 87 (100.0%) | | 211 (100.0%) | 364 (100.0%) | |

When looking at the two subgroups of related and unrelated donors, women composed the majority of donors in the related group both before and after the law (59.7% before and 57.0% after, $p = 0.662$), while men composed the majority in the unrelated group before and after the law (81.6% before and 71.3% after, $p = 0.152$).

Effect of the law on donor–recipient differences

For this analysis we used only recipients older than 18 that had a donation from an unrelated donor ($n = 159$).

Repeated-measures ANOVA of age showed a significant interaction between 'donor–patient' and time period ($p = 0.002$), i.e. the difference between donors and patient differed before and after the transplantation law.

The mean age difference between each recipient and his donor was significantly decreased from 13.5 ± 15.7 in the pre-law period to 5.7 ± 16.1 years after the law ($p = 0.02$). The rate of donors younger than 40 donating to patients older than 40 was reduced from 48.8% in the pre-law era to 31.2% after the law enactment ($p = 0.024$).

Repeated-measures ANOVA evaluating the percentage of donors with high school and below education who donated to a patient with college level and above education did not change (22.2% pre-law to 20% post-law; $p = 0.845$) as well as the percentage of unemployed donating to working patients or donors with blue-collar occupations donating to recipients holding white-collar positions (19.2% pre-law to 20% post-law; $p = 1.0$). There was also no change in the percentage of donations from

single donors to married recipients (34.1% pre-law to 21.3% post-law; $p = 0.79$).

Discussion

Three key changes in living kidney donation patterns emerge in the time period following the enactment of the Israeli transplant law: (a) the overall rise in living donations, (b) the emergence of the family as a primary pool of living donors, and (c) the change in the socio-demographic composition of living unrelated donors.

This rise in living kidney donation stands at odds with the relative decline in living kidney donations in the United States in the past decade (17). In our opinion, this change is most probably a reaction to the decrease in organ supply options for Israelis caused by the criminalization of organ trading by law, banning reimbursement of organ trade by insurance companies and the on-going effort of governments and international organizations to decrease organ sale around the world (18,19). The 2008 transplantation law has reduced dramatically the ability of patients to undergo a transplant outside Israel. Prior to the law, in the years 2005–2007, approximately 150 transplants a year were done outside Israel. These transplants comprised around 50% (446 of 892) of the total kidney transplant procedures performed on Israelis in those years. This number went down to 40 in 2010 and 35 in 2011, concomitantly with an increase in the number of patients in the transplantation waiting list from 518 in January 2007 to 733 January 2011 (7,20).

In addition to the prohibition of organ sale and tourism, the law includes a variety of measures aimed to encourage organ donation from living and deceased donors. While earning-loss reimbursement and transportation cost reimbursement, initiated in Israel by the transplantation law are not unique to Israel (21), prioritization in organ allocation to candidates who have either been registered as organ donors for at least 3 years prior to being listed as candidates, or have given their consent for actual organ donation of their deceased next-of-kin (8) is a unique clause in the Israeli law. Comparing the pre and post 2008 law periods, we found a significant increase in living donation. However, it was not until 2011 that a surge in living donation has occurred. This can be explained as a gap of internalization: it took the public 2 years to realize the new legal reality. There was also a technical issue, as the process of becoming a living donor in Israel takes at least several months.

The aid for the patients needing transplantation came mainly from their own families (Table 1). Family is a central component in Israeli society and it seems natural that people would get support from their family members: 124(58.8% of all donors) family members donated during the pre-law period and 277 (76.0% of all donors) post-law. In comparison, no change in extra-familial donation was found: 87 donors pre- and 87 donors post-law. With this increase in familial donation we see no change in the socio-demographic composition of this group. This potential "available" donor group most probably existed also in the pre-law period but the recipients in that period preferred to use the easy commercial pathway instead. This reiterates other reports that found that commercialism in organ transplantations comes instead of altruism and not in addition to it (22).

We found that women composed nearly 60% of related donors prior to and after the law; women remained recruited as the primary pool of donors for a needy family member. This "gender gap" is similar to findings from other countries (23,24).

Another finding is an increase in the donors age in the latter period. A possible disadvantage of this change may be a negative effect of higher donor age on the transplantation outcome but the difference in mean age (41.1 ± 11.1 to 44.4 ± 11.0) is small and most probably will not have a significant effect.

Another concern is whether the reduction of organ tourism and sale outside Israel, has increased illegal organ sale locally (25). If this was true, we would expect a rise in unrelated donation in the post-law period where in fact family members, who supposedly have emotional altruistic motives, composed most of the donors in the post-law increase. Furthermore, although our findings indicate no change in the volume of unrelated donations, this study suggests that the social profile of the unrelated donor has changed significantly after 2008. This new profile of

unrelated donors is far from the classic profile of the organ vendor as a young illiterate unemployed male (26). In the post-law period we found the unrelated donor population to be composed of more donors above 41 years of age, with higher education with better-paid occupations and white-collar occupations. Furthermore, since higher education most probably enables easier access to medical and administrative information and reduces donation barriers (27), a higher education level and a higher income suggests the donors in our study cohort were more informed and less needy, hinting at emotional or altruistic motives for donation rather than financial. Another indication of a non-commercial motive comes from the lack of increase in the socio-demographic gap between recipients and donors (14,15). We found a stable gap between donors and recipients concerning marital status, education and occupation. Furthermore, we found a significant reduction in the rate of donors younger than 40 donating to older patients.

Our findings, indicating an increase in living altruistic donation in lieu of pre-law commercialism, is in our opinion a key achievement of the transplant law, and is a first step in reaching the key goal in Istanbul declaration to become self sufficient in transplantation.

Another significant achievement that can be attributed to the transplantation law is an increase in deceased donation rates in Israel during the last years (20). As the gap between supply and demand is still high, we need to continue with efforts to increase kidney donation in Israel and carry on the fight against organ trade.

Acknowledgments

This study was supported by the Israel National Institute for Health Policy Research.

Disclosure

The authors of this manuscript have no conflicts of interest to disclosure as described by the *American Journal of Transplantation*.

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