A decade of continuous improvement in cadaveric organ donation: The Spanish model

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ABSTRACT: Background: There is an ever-increasing demand for cadaveric solid organs for transplantation all over the world. Partial strategies in many countries have resulted in small or transient increases in organ donation or even no improvement at all. In the early nineties, Spain started an original integrated approach designed to improve cadaveric organ donation.

Methods: In 1989 an official agency, the National Transplant Organization (ONT), and a national network of specially trained, dedicated and strongly motivated hospital physicians in charge of the whole process of organ donation, was created. The network now covers 139 hospitals.

Results: Cadaveric organ donors grew from 550 in 1989 to 1334 in 1999, a 142% increase. Cadaveric kidney transplants from 1021 to 2005 (96% increase), and total solid organs transplanted from 1302 to 3330 in ten years (156%). The rates of cadaveric organ donation per million inhabitants (33.6), kidney and liver transplantation (50.6 and 24.2) are the highest in the world.

Conclusions: Spain is the only example in the world of continuous improvement in cadaveric organ donation registered in a large country over a ten-year period. Organ shortage is not due to a lack of potential donors, but rather to a failure to turn many potential into actual donors. A proactive donor detection program performed by well trained transplant coordinators, the introduction of systematic death audits in hospitals and the combination of a positive social atmosphere with adequate economic reimbursement for the hospitals have accounted for this success. This model can be partially or totally translated to other countries if basic conditions are satisfied.

Key words: Organ donation, Transplant coordinator, The Spanish model

INTRODUCTION

For an ever-increasing number of patients with life-threatening illnesses, organ transplantation provides the best or the only hope of life. Over one million people worldwide have been transplanted and some have already survived more than 25 years (1). However, the shortage of cadaveric organ donors imposes a severe limit on the number of patients who can benefit from these forms of therapy. More than 40,000 patients are now waiting for a kidney in Western Europe, while the number of cadaveric donors is around 5,000 each year. The same can be said for the US, where the gap between the number of available organs and the patients on the waiting list is growing every year (2). Mortality rates, while waiting for a heart, liver or lung transplant, usually range between 15 and 30%, but are even higher in some reports, depending on the organ needed (2). Furthermore, there are many data on nearly all transplantable organs which show that the potential need is much higher than the reported need (3). The shortage of organs means that only the patients most likely to benefit are put on the waiting list for an organ transplant. To put patients on waiting lists who have no hope of receiving an organ is both pointless and highly questionable ethically.

There is evidence that the shortage of organ donors is not primarily the result of a lack of suitable donors, but rather the result of the failure to identify them, obtain consent and procure the organs (4). Partial strategies in many countries have resulted in mild or transient increases in organ donation or even no improvement at all (5).

Since the creation of the Spanish National Transplant...
Organization in 1989 (6), and the establishment of a national network of specifically trained, part-time, dedicated and strongly motivated hospital physicians in charge of the whole process of organ donation, Spain went from 14 to 33.6 organ donors per million people in 1999 (a 142% increase), by far the highest donor rate ever reached by a whole country. This is the only example in the world of a large country (40 million inhabitants) with a continuous increase in cadaveric organ donation sustained over a ten year period.

METHODS

Legal background

The legal background in Spain is technically similar to that of other Western countries (7, 8). Brain death is defined as "the total and irreversible loss of brain function", and must be certified by three doctors unrelated to the transplant team. Organs can only be retrieved after obtaining informed consent of the family. The law, approved in 1979, also states that no compensation can be paid either for donation or for grafted organs. No legal changes have been introduced during the nineties.

Development of the network

In September 1989, the National Transplant Organization (ONT) was created with the main objective of approaching the problem of organ shortage. From the very beginning, it was presumed that the point was not the absence of suitable donors, but a failure to convert potential into real donors. Donation / transplantation is a complex process involving different steps, which cannot be left to evolve in isolation. The ONT has led this process, acting as an official service agency and working wherever opportunities existed for improvement. During the early nineties, we developed a transplant coordinating network at three levels: national, regional and hospital or local. Most coordinators are qualified doctors, mainly intensive care specialists or nephrologists, who dedicate part of their time to transplant coordination. In 1989, there were only 25 transplant coordinating teams, but now 139 teams are active, covering practically all the hospitals with the potential for organ donation. The profile of the Spanish transplant coordinator is summarized in Table I, and is clearly different from that adopted by most other countries. They are nominated by, and report to, the hospital director (not the head of the transplant units), although functionally linked to the regional and national coordinators (9). On the contrary, the national and regional coordinators are nominated and paid by the corresponding health authorities and their role has become progressively more administrative. The central office of the ONT acts as the support agency in charge of organ sharing, transport, waiting list management, transplant registries, statistics, general and specialised information and action which can improve the whole process of organ donation and transplantation (10). Development of various training programs for health professionals, specifically dedicated to each step of the process (donor detection and management, legal aspects, family approach, organ-
sitional aspects, management of resources...), have been promoted and financed by the Health Administration (11).

Areas of improvement

Three main areas for improvement were identified: potential donor detection, donor management and approaching the family. Donor detection is the starting point and probably the most difficult step to make routine. Systematic prospective brain death registries, complemented by retrospective medical record reviews to avoid errors of over or underestimation of the potential donor pool, have been introduced in most of the regions (12-14). The methodology includes a continuous self audit process and the description of the characteristics and expected rates in every hospital. It also includes the possibility of external evaluation. Once a deficit in donor detection is shown in a particular hospital or area, a detection programme is started (10).

Failure to optimise donor management during evaluation, compliance with medical and legal requirements, and logistic preparations for retrieval can result in the loss of up to 5 donors pmp (14). Between 10 and 14% of potential donors present with hemodynamic impairment or uncontrollable sepsis which contraindicate organ donation. The promotion of research and educational programmes in close cooperation with the Spanish Intensive Care Society has been a constant activity during this decade.

Approaching the family is a key part of the process and the most sensitive, since it occurs during the human drama that the death causes. Training programmes specifically designed for this purpose, with the help of psychologists and communication experts have been developed (11) to provide adequate guidelines to transplant coordinators and other medical staff.

Communication: the role of the media

Much attention has been devoted in Spain to the effort to correctly inform the media on issues relating to organ donation and transplantation in a positive manner. Several strategies have been followed in an attempt to put to optimal use the important role of the mass media and to improve the level of information of the Spanish population on these topics:

- A 24-hour transplantation hot-line, manned by specially trained professionals, has been established using one single telephone number for the entire country.
- Periodic meetings are held between journalists, experts in communication, and opinion leaders in transplantation.

- Training courses in communication are held for regional and hospital coordinators where controversial topics, such as brain death or organ trafficking, are discussed.
- Management of adverse publicity is combined with adequate and systematic spread, via the media to the medical and lay community.

Economic aspects and management of resources

The overall budget for the three levels of the coordination network has been estimated at € 4,939,759 per year. This figure includes salaries, administrative budgets and training courses for the central office, and the extra wages of regional and the hospital coordination teams. The system is not homogeneous over the whole country, but as a general rule the budget depends on the organ donation activity of each hospital. Transplant coordinators are becoming more and more involved in the management of resources dedicated to organ donation and transplantation, especially in the biggest hospitals. Solid organ transplant costs have been calculated by a cost analysis method in several hospitals, and the mean values and total estimated costs, together with those of the coordination network and organ procurement.

Results

The number of organ donors increased steadily throughout the nineties from 550 in 1989 (14.3 donors pmp) to 1394 in 1999 (33.6 pmp) (Fig. 1). This rate compares favorably with that of all other Western countries and represents the greatest increase in organ donation for a whole country during this decade (Fig. 2). Twelve out of the 17 regions have more than 30 donors pmp and two of them have more than 50 (Cantabria 57.7 and the Basque Country 50.7). The characteristics of these donors have changed substantially because of the decrease in fatal road accidents together with the increase in the detection of older donors. Road traffic accidents decreased as the cause of organ donation from 43% in 1992 to 23% in 1999, while strokes rose from 39 to 55.4%. Consequently, the mean age of the donors went from 38 to 47.9 years, and the percentage of donors over 60 years increased from 10 to 30.3%. The family refusal rate decreased from 27.6 to 21.8%. Cadaveric kidney transplants rose from 1021 to 2005 (96% increase) (Fig. 3), and total solid organs transplanted from 1302 to 3330 in ten years (156% increase). The rates per million inhabitants of cadaveric organ donation (33.6), kidney and liver transplantation (50.6 and 24.2) are the highest in the world, and patients on the Spanish waiting list
have the best chance to receive an organ.
If the annual number of kidney transplants performed in Spain had remained stable, as in most other countries, no less than 6,400 renal patients would have not been grafted during these 10 years. The overall budget for the network dedicated to organ procurement was estimated as nearly € 5,000,000 during 1999. Estimated cost reduction in the overall renal replacement therapy budget was about € 108,000,000 in 1999. This represents practically the total cost of all solid organ transplants performed in Spain during that year.

**DISCUSSION**

After one decade of an integrated approach to improving organ donation and transplantation, Spain has more than doubled the number of organ donors, and the number of solid organ transplants is more than 2.5 times what it was at the start. Spain leads the world in organ donation and transplantation rates and is the only country where the renal waiting lists have gone down every year since 1991. It is widely recognised that the clue to this success has been the development of a transplant coordination network made up of young enthusiastic doctors, specifically trained and periodically revitalised to avoid the "burn out" syndrome. They are based in the hospital and have the improvement of organ donation as their main goal, although this is only part of their medical
work. However, the results of the Spanish Model are not comprehensible unless we look at this decade in the perspective of an integrated approach which includes an adequate legal, economic, ethical, medical and political background. We shall discuss the most relevant items of the Spanish model which, combined in an original and unusual way have enabled Spain, unique among large countries, to experience continuous improvement in cadaveric organ donation over a ten year period.

The idea that some proposed changes in legislation could resolve, in a radical and almost magical fashion, the scarcity of available organs is a recurrent topic of numerous meetings or congresses (8, 15, 16). Presumed consent seems to be effective only in specific countries such as Austria where there is an old tradition, well accepted by society, that disposal of the body is the responsibility of state, or Belgium where a significant but transient increase in organ donation was obtained after the introduction of a presumed consent law (16).

In most Western countries, even those with a theoretical presumed consent, the families are consulted and organs are definitely not recovered if the family refuses. This is the case in Spain where there is an adequate legal framework for donation and transplantation, as recommended by the Council of Europe (7, 17, 18) and other international institutions. However, the increase in organ donation during the nineties cannot be attributed to any change in Spanish legislation, which has remained unmodified since 1979.

The development of the transplant coordination network with the specific profile and characteristics described above, and its implication in all the steps of the process, is by far the most important development registered in Spain during the early nineties in the field of organ donation and transplantation. The ONT has developed a formal but flexible management structure, which ensures that the transplant coordinators who work at the “grass roots” have a sense of involvement and accountability for performance. Hospital transplant coordinators are now widely accepted as the main cause of the spectacular increase in organ donation registered in Spain during the last 10 years, and the real key to the success achieved by the Spanish Model. The combination of characteristics described is closely linked to the improvement in organ donation (19). Transplant coordinators should be doctors, (although they can be helped by nurses), especially trained, with part of their time dedicated to organ retrieval, located inside the hospital, directly answerable to the hospital director, and functionally linked to the ONT, mainly focused on improving every step of organ donation, and revitalised approximately every three to four years (in order to avoid the “burn out” syndrome, very frequent in this work, and responsible for many significant drops in organ donation in hospitals or regions). Other combinations may be acceptable, depending on the local characteristics and particularly on personal motivation and abilities, but they are not the general model which has proved its long term efficacy in Spain. This is very important because other countries are trying to adapt this model, but usually in a partial way, which will probably not be as efficient as that described.

A crucial part of the philosophy of the Spanish Model is that the universal shortage of organ donors is not wholly due to a lack of potential donors, but mainly to failure to turn many potential into actual donors. This was first based on personal experience and later substantiated by death audits performed in several regions (20, 21). A proactive donor detection programme done by the transplant coordinators was instigated in every hospital to improve donor identification rates. Death audits in hospitals were applied progressively in most of the regions to ensure that resources were used effectively and that the maximum number of organs were retrieved and transplanted (22).

Of particular importance is that about 1/3 of organ donors in Spain are detected in small hospitals without a transplant unit. This is certainly not the case in most other Western countries where most of the organs of those who die in regional hospitals are not utilised effectively. The Spanish success can be attributed to the fact that the whole process of donor detection and organ donation has been implemented in all the hospitals with ICU facilities whether or not they possess a transplant unit (19). As the Spanish rate of organ donation is over 33 donors pmp, non transplant hospitals account for no less than 11 donors pmp, that is more than the total rate of some countries of the European Union (2).

Approaching the family is a key point in the donation process, and is mandatory in Spain. Only 6% of Spanish citizens would accept retrieval of organs without eliciting the family’s wishes (10, 23). The slight decrease in family refusal rate from 27.6% in 1992 to 21.8% in 1999 can be attributed in part to the “most difficult cases” approached by the coordinators as a consequence of the much larger detection of organ donors. Some points deserve special attention regarding the approach to the family. This should be always done by specially trained staff, who have an understanding approach, and offer help and not simply a request for organ donation. The interview should be carefully prepared, and the coordinators should never show they are in a hurry or make errors such as becoming angry, not following the rhythm of assimilation of the relatives, interrupting the family, etc. Most families believe that donation provides a positive outcome from death, and helps with the grieving process.
There is a study from the south of Spain which shows that 100% of the families who agreed to donation would donate again and 30% of the families that denied a donation would have made the opposite decision a year later (24).

Data from a Spanish multicentre national survey (23) documented a significant relationship between the degree to which the public is prepared to accept organ donation, on the one hand, and the conviction that transplantation is a good and positive element of health care, on the other. Consequently, it is easy to understand that any negative broadcasts concerning such delicate matters as brain death, organ trafficking or fairness in the access of transplantation may adversely influence the public attitude towards organ donation (25). On the other hand, a good image of transplantation should facilitate the approach to the family in a significant percentage of cases. It is unwise to have much confidence in direct publicity campaigns aimed at the general population, unless a great amount of money can be invested to make a significant and sustained impact. Such efforts would have to be on a level with those of powerful companies that spend a considerable budget on publicity. Apart from some anecdotal observations, there is no evidence in the medical literature that this kind of action is really able to influence the attitude of the public positively (26). On the other hand, the scientific community tends to underestimate the power and influence of the lay media, both in a negative and a positive sense (26, 27). Managing adverse publicity and spreading adequate and positive information is a complex and demanding task which requires special dedication and professional support together with unprejudiced and close cooperation of all types of health professionals, even with those who play no part in organ donation and transplantation.

Several studies in different western countries have shown that the cost for each patient receiving dialysis is equivalent to the estimated cost of renal transplantation during the first year (28). However, after a successful transplant, the average annual cost of caring for these patients falls to less than 25%, making transplantation the most cost-effective means of caring for patients with end stage renal disease (28). If the number of cadaveric renal transplants had remained stable during the nineties, as in most western countries, 6400 patients would not have received a graft. With standard survival, this would have represented an additional cost of €108,000,000 for the year 2000. This is approximately the estimated cost of all solid organ transplants performed in Spain during 1999. Of course, the estimation of other benefits not strictly economic derived from renal and especially vital solid organ transplants are easy to understand although difficult to evaluate.

In 1995, after a careful evaluation of the system, the South Australian Ministry for Health recommended the adoption of the Spanish Model in South Australia. Since the introduction of the modified Spanish model, the organ donation rate in South Australia is double the rate of the rest of Australia (29). More recently, the Parliament of Western Australia has also recommended this approach (29). Likewise, the region of Tuscany in the North of Italy doubled its organ donation rate in only one year after the implementation of the Spanish Model (30). Other countries and/or regions from Western Europe and Latin America have followed this system in a partial way with different results mainly dependent on the official and professional support received in every case. A national health service with full coverage of the population and enough ICU facilities seem to be necessary conditions to successfully translate the Spanish Model to other countries.

The Spanish organ donation rates are the results of the efforts to overcome the obstacles met in every step of the process, in every region of the country, and in every hospital. This means an integrated approach and the need for a well trained, well motivated in-hospital coordinating network which now covers practically all the public Spanish hospitals. The results achieved over a ten year period are very clear and show that the problem of organ shortage is not a lack of potential donors but, rather, a failure to turn potential into real donors. Sustained high organ donation rates are never the result of fate or chance, but of the work and effort of the whole Health System together with the solidarity of the population. Health professionals need support from their respective administrations in order to obtain the organisational structure that will make organ donation possible. Depending on the characteristics of the different health systems, this model can be partially or totally extrapolated to other countries.

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