Regional Experiences of Tissue Donation and Forensic Medicine in Hamburg – Results of a 5-Year Period

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Keywords

Tissue donation · Tissue transplants ·
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Summary

Objective: We present the operational organization and daily workflow of our Hamburg model and the results of the years 2007–2011 concerning donation of corneas, musculoskeletal and, since 2010, cardiovascular tissues. **Methods:** Each of the about 3,600 deceased every year undergoes an evaluation process by two coordinators on duty, the tissue coordinator and the family coordinator. All donation connected issues are carried out within the standardized protocols of a quality management system and documented in a special data base. Two catamnestic surveys evaluated the satisfaction of donor families retrospectively. The inclusion rate for cornea donation was 23% and for musculoskeletal donation 10%, with a decrease after the 75 years age restriction of musculoskeletal donors in 2011 defined by the contracting tissue bank German Institute for Cell and Tissue Replacement gGmbH (DIZG), Berlin. **Results:** Since 2007 1,268 corneas were explanted altogether, reflecting an increasing explantation rate from 156 (University Medical Center Hamburg-Eppendorf (UMC: 9) in 2007 up to 304 (UMC: 52) in 2011. Overall 173 musculoskeletal donors (5 years) and 11 cardiovascular donors (2 years) spent tissues. The consent rate was much higher. The evaluation of the families reflected a positive feedback for the guiding of the donation process. **Conclusion:** Forensic institutes can act as an interface between donors and recipients without neglecting forensic investigations. They are uniquely positioned to recognize potential donors. In addition, the contact with a physician of the forensic institute may help families during the mourning phase.

Schlüsselwörter

Gewebespende · Gewebetransplantat ·
Forensisches Institut · Gewebespendenergebnisse

Zusammenfassung

Hintergrund: Wir stellen den seit 2007 etablierten Organisationsrahmen und täglichen Arbeitsablauf im rechtsmedizinischen Institut in Hamburg in Bezug auf die Erkennung und Realisierung postmortaler Spenden von Augenhornhäuten, muskuloskelettalen und kardiovaskulären (erst seit 2010) Geweben sowie die Ergebnisse der letzten 5 Jahre vor. **Methoden:** Jeder der jährlich zirka 3600 eingelieferten Verstorbenen wird einem Screening hinsichtlich einer potentiellen Spende unterzogen; dabei arbeiten ein Gewebekoordinator und ein Familienkoordinator Hand in Hand. Die Einschlussrate für die Corneaspende betrug 23% und für die muskuloskelettale Spende 10% (mit einem Rückgang seit der Begrenzung des Spenderhöchstalters für muskuloskelettale Gewebe durch die kooperierende Gewebebank auf das 75. Lebensjahr im Jahr 2011). **Ergebnisse:** Seit 2007 wurden insgesamt 1268 Corneae explantiert, und zwar mit zunehmenden Spenderzahlen von 156 (University Medical Center Hamburg-Eppendorf (UMC: 9) im Jahr 2007 bis zu 304 (UMC: 52) im Jahr 2011. In diesem Zeitraum wurden darüber hinaus 173 muskuloskelettale und in den Jahren 2010/2011 11 kardiovaskuläre Spenden durchgeführt bei einer deutlich höheren Zustimmungsrate (z.B. 64 in 2011). Die Spenderangehörigen äußerten sich 1 Jahr nach der Spende zufrieden über alle damit verbundenen Prozesse. **Schlussfolgerung:** Dies zeigt, dass ein rechtsmedizinisches Institut ohne Kollision mit seinen forensischen Aufgaben als ideale Schnittstelle in der Erkennung und Realisierung von Gewebespenden agieren kann. Darüber hinaus können trauernde Angehörige im Gespräch mit einem Arzt des Instituts hilfreiche Unterstützung erfahren.

Introduction

All deceased persons from the metropolitan area of the City State of Hamburg (approximately 2,700 every year) in whom the manner of death is certified to be unnatural or undetermined are brought to the Hamburg Institute of Legal Medicine. On behalf of the public prosecutor either a medicolegal autopsy has to be carried out or the body is released for burial. For organizational reasons the institute serves also as the morgue for deceased patients of the University Medical Center Hamburg-Eppendorf (UMC) amounting to about 900 cases per annum.

Post mortem tissue donation – in a narrower sense cornea donation – has a 30-year tradition. Since 2007 musculoskeletal tissues and since 2010 cardiovascular tissues can be harvested too. The main tasks in the donation field are, besides public information, the identification of donors, the grant of the ‘informed consent’ by the relatives and the contact to an institution that performs the harvesting of the tissues [3, 6]. Institutions such as the Institute of Legal Medicine can hold a key position to enable tissue donation in accordance with the deceased’s last will, the German Tissue Act (Gewebegesetz, 2007) as well as with cultural and ethical standards [4].

Do Legal Requirements and the Process of Tissue Donation Interfere?

In forensic cases no alterations can be carried out on the body in the period before the decision of the public prosecutor. On the other hand the German Tissue Act requests a blood sampling for serological screening within 24 h post mortem and the removal of musculoskeletal and cardiovascular tissues within a 36-hour period post mortem after an ‘informed consent’ has been granted by the family. So the daily workflow of a forensic pathologist, being the so called tissue coordinator, and a family coordinator has to be organized both working hand in hand (fig. 1).

This model has been unique so far in Germany, even though a similar one has been established in Munich. Essential components are the cooperation with the authorities and the non-profit German Institute for Cell and Tissue Replacement (gGmbH DIZG) in Berlin that guarantees the required quality management system for musculoskeletal donations.

Material and Methods

Process of Evaluation for Donation

Since 5 years, a special database is used for the selection process of every incoming dead body using the following inclusion criteria:

- Level 1 means that no obvious exclusion criterion was found in the documents or on the body and that the cooling interval of 6 h post mortem had been observed.
- Level 2 means that the social and medical history gives no reason for exclusion.

Often no legal time of death is known, because the body has been found at the scene. In order to judge the cooling interval the time of death can be estimated by rectal temperature of the body, the rigor mortis, the electric excitability of the *Musculus orbicularis oculi*, and the state of the livores. The family coordinator cares for the next of kin’s consent for donation, who is usually contacted by phone; the contact data are delivered by the police. If the family takes donation into account, a second telephone call 1 or 2 h later is offered in order to discuss questions that might have been raised in the meantime and come to a definitive decision [6]. But if the next of kin is overstrained and a highly developed mourning reaction has come to the fore, an informed consent cannot be granted. If necessary, psychotraumatologic counseling support can be arranged within a few days.

The authorities in Hamburg usually guarantee a limited acceptance for tissue explantation if no hindrances for the legal investigation are expected and the narrow time frame for retrieval threatens to elapse. In the case of the necessity of a medicolegal autopsy this can be performed in connection with tissue donation.

Organizational Changes since 2007

In order to improve the next of kin’s acceptance and the procedures for explantation and preservation, in 2008 the explantation of the bulbi was

Fig. 1. Daily workflow: assessment for tissue donation. pm = Post mortem.

Fig. 2. Cornea donors from the forensic institute and the UMC.

replaced by the donation of the corneoscleral disc, in 2009 the cornea bank became part of the Institute of Legal Medicine, in 2010 a co-worker of the institute has been charged with the tissue donation coordination for the UMC, which is followed by a close cooperation with the transplant coordinator on the intensive care unit and a change of the process for patients who died within the hospital: Every doctor is obliged to ask the relatives for a donor card of the deceased. This led to a remarkably higher number of donated corneas, but not musculoskeletal or cardiovascular tissues because of the often existing exclusion criteria in the patients' health history. In contrast to what has been described by Nitschke et al. in 2008 [10], tissue donation from multiorgan donors has only been performed in few cases up to now. Since 2009, tests for HIV, HBV, HCV antibodies as part of the required laboratory testing program are performed before the removal of musculoskeletal and cardiovascular tissues.

Results

Cornea Donation

After the German Tissue Act came into effect in 2007, a decrease of donations resulted. This led to a reorganization of the strategy concerning blood sampling and next of kin contact and, in 2008, the cornea explantation. As shown in figure 2, the percentage of cornea donors rose steadily, though not yet all physicians and departments of the hospital manage to assure the exploration of the last will after a patient's death. The inclusion rate referring to all incoming bodies was 23% in 2011 and 21.8% in 2008/2009, what is nearly the rate of 26% mentioned by Pont et al. in 2003 [8].

Figure 2 shows the statistics of the cornea bank over the period of donation of the corneoscleral disc since 2008.

Musculoskeletal Donation

Since 2007, we had 173 donors altogether. Donors from the UMC wards (9 in 2010, 6 in 2011) are rare because of the poor health status and the often infectious situation [3] of the patients. The number of consents was much higher (64 consents in 2011), but organizational problems as well as secondary medical exclusion criteria mentioned by the general practitioner or the family led to the decreased numbers mentioned above. The inclusion rate for musculoskeletal donation was 8.3% in 2011 and 8.5% in 2008/2009. As reported by Edler et al. [2] for the last mentioned period, 85.7% of the bodies had

Fig. 3. Retrospective assessment of the donation process by the donors' relatives: 'Answers to all my questions'. ms = Musculoskeletal donation; c = cornea.

Fig. 4. Retrospective assessment of the donation process by the donors' relatives: 'I drew comfort because the donation helped patients'. ms = Musculoskeletal donation; c = cornea.

to be excluded from musculoskeletal donation before contacting the next of kin: 24.7% had signs of decay, 9.3% had not been cooled within 6 h, in 12.2% the blood sampling could not be performed within 24 h, 15.2% had medical exclusion criteria, and in 13.1% process hindrances, e.g. no family contact, led to deferral. In 11.2% coincidentally occurring obligations of the staff or documentation gaps were observed.

The relatives presented a high degree of satisfaction with our guidance of consenting processes in two catamnestic studies that covered a 1-year period of musculoskeletal donors [7] and cornea donors [9], referring to 26 and 112 next of kin interviews, respectively. More than 90% of the musculoskeletal donors' relatives felt that their questions concerning donation and the circumstances of death had been answered completely during the telephone call (fig. 3); a similar rate (85% of families of cornea donors) evaluated donation as a consolation in the mourning process because it meant help for the living patients (fig. 4).

Cardiovascular Donation

When the cardiovascular donation program for heart valves was started on September 1, 2010, the most challenging point

besides the special training for the removal technique was to control sterility in an autopsy room by observing the quality management rules of the contracting tissue banks. The 4 donors in 2010 showed an acceptable microbiologic result, while at least 3 of the 7 donors of 2011 (on the base of 17 consents) were not acceptable. In 2012 (9 donors up to August) we know of 2 donors whose tissues had to be discarded because they were infected, either from the body or the surrounding.

Discussion

The legal framework of the German Tissue Act 2007 with its high demands for the consenting process, the medical screening of potential donors, and the quality of the tissue transplants led to considerable efforts concerning personal and financial resources in order to meet the safety and quality requirements for consent, procurement, storage, and delivery. After 5 years of experience we have not yet reached the numbers of donors that we expected to have though the consent rate is satisfying. The confounding factors are:

- human resources, because the more time-consuming removal of musculoskeletal tissues by the specialized forensic pathologists team collides more often with other tasks of the staff than the removal of the cornea,
- the limitation of the donor age to 75 years in the last quarter of 2011,
- the influence of the public discussion on donation and the next of kin's decision, and
- the uncertainty of the relatives.

Up to now only very few relatives know if donation is consistent with the last will of the deceased person. We expect the revision of the German Transplantation Act in 2012 to be helpful because now German citizens are regularly reminded to decide on organ and tissue donation.

'Primum nihil nocere' is part of a physician's self-concept. Our data show that asking the relatives for the deceased's last will concerning donation means no additional emotional bur-

den for them if the question is placed appropriately. The challenge to communicate between solicitousness, mutual understanding of the deceased's last will, and clarification of tissue donation conforming to the law persists in institutions such as the Institute of Legal Medicine, particularly with cases of sudden unexpected deaths every day [1, 5, 9].

On the local level, we convinced partners in Hamburg, for example several hospitals, to participate in our program; however, up to now with only limited success. The networking in Germany with different organizations seems to be more effective. Scientific exchange of knowledge and further standardized development of procedures will be helpful.

Conclusion

- Forensic institutes can serve as places to identify tissue donors and take care for appropriate procedures, but they need more resources and organizational support. The processes are too complicated to depend on single person's activity only.
- Transplant centers have to pay more attention to the donor side in order to align the interests of the donor with those of the recipient.
- The scattered institutions for tissue donation in Germany can be more effective by increasing the cooperation between them. We suggest a central German telephone number ('Call Center') and one center for harvesting the tissues in every federal state that interacts with a mobile team to cover the area.
- Tissue transplants are needed badly. The authorities and the Federal Center for Health Education (Bundeszentrale für gesundheitliche Aufklärung) are required to find options and answers to this problem.

Disclosure Statement

The authors have no conflicts of interests to declare.

References

- 1 Bredehorn T, Langer C, Eichhorst A, Bormke D, Wachsmuth C: Questioning the relatives for organ and tissue donation. *Transpl. Proc* 2002;34:2353–2354.
- 2 Edler C, Wulff B, Heinemann A, Wilke N, Klein A, Montenero M, Schröder AS, Schrot M: Post mortem Tissue Donation: Pathways from Identification of Potential Donors to Accomplished Donation. Foundation of the European Tissue Banks, Annual Report 2011. Hamburg, Verlag Dr. Kovač, 2012, pp 43–53.
- 3 Pruss A, Katthagen BD: Muskuloskeletal tissue banks. Legal foundations and graft safety. *Orthopädie* 2008;37:749–755.
- 4 Püschel K, Bratzke H, Graw M, Wulff B: Positionspapier der Deutschen Gesellschaft für Rechtsmedizin zur Förderung der postmortalen Gewebespende. *Rechtsmedizin* 2010;20:61–62.
- 5 Schirmer J., Roza Bde A: Family, patients and organ and tissue donation: who decides? *Transpl Proc* 2008;40:1037–1040.
- 6 Wulff B, Zechmeister EM, Görndt J, Axel J, Münchow M, Püschel K: Entscheidend ist der Letzte Wille. *Hamburger Ärzteblatt* 2010;11:28.
- 7 Wulff B, Meins S, Heinemann A, Edler C, Püschel K: Die muskuloskelettale Gewebespende: Rückblickende Bewertung durch die Angehörigen des Spenders im Jahresabstand nach dem Tod. *Arch Krim* 2012;229:107–116.
- 8 Pont T, Gràcia RM, Valdés C, Nieto C, Rodellar L, Arancibia I, Deulofeu Vilarnau R: Theoretic rates of potential tissue donation in a university hospital. *Transplant Proc* 2003;35:1640–1641.
- 9 Müller K: Angehörigenespräche in der Rechtsmedizin – ein Spagat zwischen Trauerbegegnung und der «Akquise» postmortaler Hornhautspenden? Medizinische Dissertation, Universität Hamburg, 2012.
- 10 Nitschke F-P, Kalus U, Pruß A: Überlegungen zur zukünftigen Umsetzung des Gewebegesetzes im Spendebereich – Erfahrungen bei der Gewebespende und -entnahme im Rahmen der Organspende in der DSO-Region Nord-Ost. *Transfus Med Hemother* 2008;35:464–470.