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The potentiality of the archives of surgical pathology as biobanks

Abstract

In recent years new molecular biology techniques have emphasized changes in cancer research and important advances in genomic and proteomic fields have led to the need to develop tissue banks for research purpose. Since pathology departments must store tissue blocks for many years, the biomaterial stored in their archives can represent a very useful tool for research. However, the lack of specific laws and the absence of an explicit consensus to the use of these specimens for research purposes cause many difficulties. We must also notice that, sometimes, for these tissues it is particularly difficult to obtain an "a posteriori" consensus, because many subjects could be dead or unavailable. On May 1st 2012 "The Italian Privacy Authority" established that, when the involved person is unavailable or dead, this kind of samples can be used for research purposes without a consent or, as an alternative, in anonymous way. We would like to underlie both the importance of histopathology specimens in cancer research and the essential role of the pathologists because they are the only ones that can recognize and classify pathological tissues, ensure that the tissue removals for research projects do not compromise the diagnosis and the analysis of the resection margins.

Keywords: surgical pathology, bio-banks, formalin-fixed paraffin-embedded specimens, consensus, biomaterials

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Introduction

The recent advances in genomics and proteomics, together with the increasing demands for biomarker validation studies, have emphasized changes in the field of cancer research, fueling the development of tissue banks for translational research. For these reasons, in recent years there is a considerable increasing of interest in bio-banks. Bio-banks-collections of biological material in use for research-vary in size, scope and focus. Samples that belong to biobanks can be collected from generic population, from patients who had surgery or a biopsy and also from people who have recently died. All Hospital Units of Surgical Pathology collect many type of human tissues (from surgery and autopsy) and so biomaterial stored in their archives can represent a very useful tool for research. However the controversy about the use, for research purpose, of organs and tissues removed during the autopsy required the Scientific Community to discuss about the ethical and legal implications about this topic.

Histological techniques

Units of Surgical Pathology can receive four different types of tissue: Incisional biopsy (a portion of tissue from a large lesion); Excisional Biopsy (if the entire lesion is removed, usually with a rim of normal tissue); Punch Biopsy/Core Needle Biopsy (performed by biopsy forceps or with special type of biopsy needle), Surgical Specimens (as results of a major surgical procedure).[1] The routine work associated with a surgical pathology includes gross and microscopic examination of the sample. The first step of gross identification is a general inspection, proper identification and orientation of the sample with identification of all of its normal and abnormal components. After gross examination, samples must be set up for microscopic examination. The aim of histological technique is to preserve microscopic anatomy of tissue and make samples able to be cut into very thin slices. This is achieved by a series of processes: fixation, dehydration, clearing, impregnation, blocking, cutting, staining. The final products of these processes are blocks and sections. For the most part of cases, only a little portion of the surgical sample is used for diagnostics purpose. The rest of the sample can be defined as "excess" (i.e. tissue not specifically removed for research nor material essential for routine diagnosis and staging purposes), whose scientific potential is enormous.[2] Blocks and sections can be stored indefinitely. In many Countries there are laws that establish how and how long pathology departments and hospitals must store biomaterial. For example, Joint Pathology Center in Silver Spring, Maryland, holds 28million of blocks, dating back to the First World War. Italian law establishes that tissue pathology slides must be stored for 20years. We also would like to underlie that since the storage costs are very expensive, the use of these biomaterials as research resource could be a valid solutions to minimize this problem. However there are many aspects to be considered. Legal aspects about tissue ownership, tissue block and slides possession are still under discussion. In U.S.A, some States have regulatory laws that establish that the Hospital owns about slides and blocks even if all the informations that can be drawn from them belong to the patient while in other States laws establish that patients owns about both aspects. Currently, for research purpose, a Pathology Department can give an unstained sections from paraffin block (as thin slides or a portion of free sample in small tubes) while it stores the whole block: sometimes researchers, in order to study a specific pathology, need to use samples in which patients are not identified. In conclusions, the archives of the Units of Surgical Pathology are collections of biomaterials whit a very precious scientific value and they could represent an important resource for researchers but the lack of a consensus has always represented a critical element. For this kind of samples is particularly difficult to obtain an "a posteriori" consensus, since many subjects might be dead or otherwise unavailable. We firmly believe that paraffin blocks, microscopic slides, and reports should be kept permanently, regardless of what the minimum state requirement might be.[3]

Molecular biology analysis

In the last decade, molecular biology and its related techniques became an important part of Surgical Pathology analysis, so allowing analyzing the viral and bacterial DNA, such as mycobacterium tuberculosis or human papillomavirus (HPV), in cytology or biopsy specimens. The numerous molecular biology techniques allow studying molecular pathology through the use of high sensitivity and specificity analysis, such as the study of DNA. Among these innovative techniques, the most important methods of molecular biology are represented by in situ hybridization (probes directed against a specific DNA or RNA sequences in a tissue) and PCR (polymerase chain reactions in order to amplify a target DNA sequence).[4] Mutational analysis allows to acquire the genetic information contained in altered DNA. Moreover, there is the possibility to perform new future investigations and tests on the same sample.

Stored tissues in surgical pathology archive for diagnostic purposes

In the archives of Surgical Pathology Institutes, tissues are stored for diagnostic purposes, without an explicit consent for research aims. For this reasons, although these archives could represent a rich collection of biomaterials with a very precious scientific value, they cannot be considered bio-banks with a research aim because the patient consent is acquired only for diagnostic and therapeutic purposes. It is easy to understand that the possibility to use these biomaterials for research has always been a crucial topic but the lack of consent represents an insuperable limit and it is one of the main discussing issues.[5] In addition acquiring the consent after the procedure has been carried out (in order to access to the samples) sometimes is quite difficult, because many subjects might be dead or otherwise unavailable. In Italy, the latest "Authorization of the Privacy Authority", on May 1st, 2012, introduced some important new topics: the law has been modified concerning the impossibility to inform involved people and allowing researchers to use the samples for research purposes without consent when the involved person is unavailable or dead. As an alternative, biomaterials for research can be used only anonymously. Anonymous samples are defined as those samples that associated data cannot allow to identify the person to whom they belong.[6]

Italian issues

At present informed consent concerning the conservation and use of human tissues for research purposes is the main topic of discussion. The lack of laws in the field of human biological samples treatment and bio-banks for research purpose causes numerous uncertainties. At this moment, Italy applies the current law about personal data. This law has been updated in 2007 by the Privacy Authority, dealing with the treatment of genetic data, in particular in matter of using biological samples as source of this type of data. However, this current legislation is considered quite inadequate. The necessity and the right of the patient to decide whether to give the consent (consent defined by the Privacy Authority as detailed, independent and informed) is an essential principle that must be respected. But it is quite difficult to obtain the consent to use the samples for research aims by those people who underwent the sampling many years before and whose samples are stored in the archives of anatomic pathology institutes. Secondly, it must be considered that the samples stored in the bio-banks could be used for several and often non-definable future research projects. For this reason, since it is possible that many years could pass between the sampling and the use of the sample for research, it is difficult to submit an adequate consent form to the patient and inform him/her about all the details concerning a future research. In this problematic overview, the Legislator worsened the situation rather than establish the expected discipline in matter of the use of human tissues and bio-banks. In fact, the recent reform of intellectual property Code (deliberation of the council of ministers, July 30th, 2010), art. 170-ter, states that "everyone who uses human biological material for research and invention purposes, being aware of the lack of a specific consent given by the involved person, is punished with a penalty from 100000 to 1000000 Euros". In this framework, there are thousands biological samples, potentially essential for research, stored in the Italian bio-banks without a covering consent form and unused because of the threat stated in the reformed intellectual property Code.

The consent for research purposes-donation

Three crucial points must be cleared in the request and acquisition of informed consent for research purposes donation of biological samples:

I. Consent to sampling;

II. Consent to research aim;

III. Consent to personal data treatment.

The first point is the prerequisite for the others, but it is not permanent because it would be meaningless to revoke the consent after the tissue has been sampled. It is the usual medical informed consent, although the content of information and its specificity are still discussed.

The second point is the most important one. When someone decides and agrees to the research use of his/her sample, if no wage was given, it appears as a donation, even if the donor is not impoverished and the object is not a part of his/her patrimony. It is considered unethical to give the donor a reward that is different from a costs refund. Once the samples are consigned to the bio-bank, how is it possible to prevent abuses and protect the intention of the donor? In the current lack of specific laws, it is possible to apply the civil code, art. 793, which states that the donor, according to his/her will, can limit the use of his/her sample. The civil code also states that "whoever is interested in the matter" (researchers, for example) is obliged to behave in accordance with the donor's will. The third point is a privacy problem and it does not involve the donation: the donor must always be informed and asked about which level of anonymity he/she desires and if he/she wants to be informed about the results of the research. The consent to personal data treatment is revocable at any time, while the donation to the bio-bank (once the sample has been taken) is irreversible. If the consent for research purposes is revoked by the donor, the possible solution could be the destruction of the sample or making it anonymous. The latter would be more advisable. In contrast with the most widespread opinion, it is our belief that the consent should be given not for a specific modality of research, but for research aims in general, "gratia artis" and for a common useful aim. Moreover, it is unlikely that the donor could understand the specific terms of a scientific research and therefore limiting the consent to a specific research protocol would mean preparing and acquiring a new consent for each possible future step. This would be difficult to achieve and would cause many difficulties to the donor. On the other hand, there are the samples collected during diagnostic or therapeutic procedures, without the possibility to ask the

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consent for research and personal data treatment. These samples are normally destroyed, while they may represent an important resource, provided that they become anonymous, so making the identity of the person they belong untraceable. Otherwise, for samples which are not explicitly addressed to conservation and research, a clear refusal should be acquired. In this way, if the person decides not to donate his/her sample for research purposes, his/her would be respected by destroying the samples.

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Conflicts of interest

The author declares that there are no conflicts of interest.

References

1. Lowe DG, Jeffrey IM. Surgery Pathology Technique, 1st ed. *BC Decker, Philadelphia, USA*. 1990.
2. Rosai St Louis J, Mosby MO. *Rosai and Ackerman's Surgical Pathology, 9th ed*. 2004;35(12):1572.
3. Robbins, Stanley L, Vinay Kumar. Robbins and Cotran pathologic basis of disease. 8th ed. *Saunders/Elsevier, Philadelphia, USA*. 2010;1450.
4. Allen DC, Cameron R. Histopathology Specimens: Clinical, Pathological and Laboratory Aspects, 1st ed. *Springer-Verlag, London, UK*. 2004;520.
5. LiVolsi VA. Use of human tissue blocks for research. *Am J Clin Pathol*. 1996;105(3):260–261.
6. Baker M. Biorepositories: Building better biobanks. *Nature*. 2012;486(7401):141–146.