NHS BLOOD AND TRANSPLANT

MULTI-VISCERAL AND COMPOSITE TISSUE ADVISORY GROUP

Governance Report for MCTAG – October 2017

A keyword search was performed, identifying only 4 incidents linked to the term "Bowel". We do not yet have a formal method to capture incidents related to other vascularized tissues.

Two of the Incidents were of no importance – the bowel was peripheral to other issues.

In one case, it was reported that the recipient developed TB two months after multi visceral transplant. No known risk factors from donor and early indications were that this was reactivation of latent TB in recipient.

After investigation, this initial presumption was further supported. The histology results of the recipient's removed small bowel (not the transplanted) showed granulomas which is consistent with a latent infection. No other recipients have developed TB and as mentioned there were no risk factors associated with the donor.

All indications are that this was not donor transmitted and most likely a reactivation in a latent infection within the recipient.

In another case, frozen section performed on ovary- reported as benign, further testing on fallopian tube has identified (6 days post donation) a serous adenocarcinoma. This was identified post transplantation of right kidney, liver and abdominal wall.

The conclusion was that the malignancy was low grade and probably restricted to the Fallopian Tube. After considerable discussion, all centres have decided to leave the organs in situ. There were two concerns:

One surrounded the lack of communication about the biopsy being performed. This whole area is being explored, and a more robust request and tracing system for donor tissue biopsies will be introduced before the end of the year.

In addition, there was no HTA form for the abdominal wall transplant. Also whilst NHSBT have a system to provide traceability for this type of transplant, it is not 'coded' within NTxD in the same fashion as other organs and whilst the traceability is present, it is not as clear. This meant that whilst the abdominal wall centre were informed of the result there was a delay (although not significant).

These points raise a number of Governance issue in vascularized tissue transplants. When the abdominal wall is transplanted with a liver, in a multivisceral transplant or with small bowel, it is regarded as a component of that transplant. It is analogous to the iliac artery being implanted, to aid the transplant, with a kidney. Therefore any traceability is linked to the 'main' transplant (liver, MV or small bowel).

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But if abdominal wall is to be transplanted separately, as seems to be the case in this Incident, then we need to ensure that the traceability is clear to allow for centres to be contacted as necessary. As such the following actions are required:

1. Ensure that the abdominal wall is documented in the 'other' section on an abdominal organ HTA A form to ensure it is clear it has been retrieved.
2. Completion of a HTA B form by the transplant centre that is sent to NHSBT to allow for the recipient details to be captured.
3. NHSBT to ensure that the current traceability system is as robust as possible.
4. NHSBT to amend NTxD so that it allows the same system of traceability as all other organs.
5. MCTAG to consider allocation rules; less important, but due to an increasing need this should be reviewed to prevent future allocation disputes.

As well as the above, there is also ongoing work with the HTA regarding the regulatory requirements when accessory tissues (e.g. rectus muscle fascia and blood vessels) are used to support organ transplantation in secondary recipients (who have not received an organ from the same donor). According to the regulations, such transplants should be carried out in accordance with tissues and cells regulations. Following discussion between NHSBT, a clinical representative, and the HTA, the HTA have agreed that fascia used in secondary recipients may be treated as an accessory tissue, under ODT Regulations, as an interim solution. Traceability should be captured in the same way as for abdominal wall.

The HTA will develop a framework to cover fascia and other tissues currently procured in theatres by NORS teams (vessels, islets, hepatocytes etc). NHSBT and clinicians will be involved in this process to advise HTA on what is operationally / clinically viable.

John Dark
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