RESPONSE TO TGA DISCUSSION PAPER ON:

REGULATION OF AUTOLOGOUS STEM CELL THERAPIES

by

EXECUTIVE* of

NSW STEM CELL NETWORK

Efficacy

We note the increasing use of autologous cells, especially those obtained from lipoaspirates, to try and treat a variety of medical conditions but especially traumatic injuries, especially of sports players, and degenerative conditions, especially of knees.

Whilst there are no published studies we are aware of that demonstrate efficacy of the treatment in humans, we are aware of a number of sports stars that appear to have benefitted from the receiving such cell applications[1]. Through the media, we are also aware of members of the public who received no such benefit.

We are also aware of a published study[2] that demonstrates regrowth of cartilage in the knee joints of individuals with osteoarthritis given intra-articular injections of autologous mesenchymal stem cells (1×10^8 cells) prepared from lipoaspirates.

We would reasonably expect those applying these cells to people should be aiming to confirm efficacy in a double blind trial, perhaps using people with injuries that the practising clinicians are best likely to respond to the injected cells. Such people might be those who have experienced acute trauma, or those with osteoarthritis and who have residual cartilage that might respond to growth factors released by the injected cells.

A double blind trial with lipoaspirates injected into knee joints of those with osteoarthritis was conducted at the Royal North Shore Hospital in Sydney, funded by the company Regeneus. It showed no significant difference either in pain or MRI features between the treatment and placebo groups[3], although there were changes in reference biomarkers. It is possible a different outcome might have been achieved if the recipients were selected using different criteria, for example those with greater amounts of residual cartilage, and further studies of this type need to be encouraged.

Patient demand

Patient demand is a major factor driving the use of autologous and other cell treatments [4]. They want something that current treatments are not providing / cannot provide. Potential recipients are prepared to pay up to $9,000 for cell applications, but, as with any customer, let the buyer beware. Informed consent seems not to be an issue, as there have been few reported complaints to the authorities [5,6]. This is despite the brevity of some Patient Information Sheet and Consent Forms, which would be extremely unlikely to be approved by a Human Research Ethics Committee.

It is claimed by some that gullible people are being wrong influenced to pay their money and receive autologous cell administration. Better education of the community should reduce this risk.

Innovation vs Safety

It is important not to stifle innovation by putting it beyond the reach of those wishing to be inventive. As is noted in the TGA Discussion Paper[5], there is a concern that involvement of the TGA at this early

stage of the autologous cell therapy may inhibit those wishing to promote the industry. Of course, if the track record of autologous cell transplants was poor as regards safety, then the equation would change and more TGA involvement should be encouraged to reduce risk. But safety seems not to be a major issue at present, at least based on what has been reported to date, and this is also noted in the TGA Discussion Paper.

Advertising

Promotion of autologous cell treatments is carried out in a number of ways. Patients talking to one another is a key method of communication for this form of treatment, as it is with all other aspects of medicine. However, it is the internet where unproven claims that may seem a little fanciful to the sceptic or the more informed person appear[6,7]. Some clinicians advise they are experts in the area, but appear to have limited experience. It is in this area of advertising that tightening up should be carried out not to mislead members of the public. There are reasonable guidelines already in existence, via AHPRA, which would address this issue, but they will need better implementation if the standard of advertising is to be improved.

Code of Conduct

We have supported a move by a consortium of Australasian autologous users to create a self-regulated Code of Conduct[8]. We understand key strategies of this Code are:

1. Manufacturing according to internationally defined standards;
2. Advertising in line with AHPRA guidelines;
3. Practising evidence based medicine; and
4. Obtaining informed consent.
5. Practitioners are appropriately trained.

We understand that the 1st draft of this Code has been created, and that it has been sent to the TGA for comments.

Recommendations

In view of all of the above, we suggest the following courses of action to improve the current situation re autologous cell treatments:

1. AHPRA be requested to review the advertising being carried out by clinics promoting autologous cell treatments, and officials from this organization be asked to guide those who are deemed to be in breach of the regulations to improve. Repeated offenders should be prosecuted.

2. Support the establishment of a self-regulated Code of Conduct, and suggest that it also include mandatory reporting of Adverse Events.

3. Monitor the outcome of the Code of Conduct on an annual basis.

4. Educate health and medical practitioners about stem cells and their uses.

5. Educate the general public about stem cells and their uses.

6. The TGA make no change to the current regulations (Option 1), which excludes autologous stem cell therapies from regulation as therapeutic goods, and is akin to how bone marrow transplants are regulated in Australia.

7. Review of progress in the field occur in 3 years (January 2018), with a view to determining if there should be a recommendation to COAG to tighten the rules and no longer exclude stem cell therapies from regulation as therapeutic goods.

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  - Dr Kelvin Hopper
  - Associate Professor Ian Kerridge
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