Participating in clinical trials:

masculinity, stem cells and heart disease

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One of the ways to understand the many trajectories of aging is to focus on individuals who have, for a variety of reasons, enjoyed privileged access to health care and are therefore able to envisage an aging process that would not otherwise have been possible. This article is based on interviews conducted with men aged 53 to 77, living in a major Canadian city, who suffered serious heart incidents and subsequently took part in a clinical trial program involving the use of stem cells. As a result of their participation in this program, these men have new hope for the future, are able to make concrete plans and can entertain the possibility of aging "in good health."

Given that a heart damaged by a heart attack cannot be repaired, because the tissue is scarred, mechanical devices (cardiac stents, bypasses) and medications (e.g., beta blockers) are used to keep the organ minimally functional. Heart transplants are a possible, although less attractive alternative, because of serious risks, including complications arising from immunosuppressive therapy. There is also a shortage of donors. Although the number of myocardial infarctions has diminished in recent years (the reduction has been more marked in Western Canada than in the Maritimes and Quebec), it is estimated that more than 500,000 Canadians are currently living with heart disease, with 50,000 new patients diagnosed each year[1]. Despite all the available treatment modalities, only 50% of patients who have suffered a heart attack survive five years after the event.

Another possible solution is an operation using autologous stem cells (taken from the patient's body) in order to regenerate muscle tissue. This procedure avoids thorny ethical issues (strong opposition to the use of embryonic stem cells) and immunological problems (no immunosuppressive therapy is required, because the patient is his/her own donor). Unfortunately, some 100 clinical trials conducted worldwide on the use of stem cells to treat cardiac patients have yielded mixed results. Some patients enjoyed improved health compared to participants in the placebo cohort, while others saw no change. These trials have nonetheless demonstrated the safety of these procedures. They also show the tremendous potential of this type of medical technology, since tests on animals have produced positive results and trials on humans have been moderately successful[2]. However, a recent article[3] reached devastating conclusions for proponents of stem cell procedures.

After analyzing a number of discrepancies in publications on stem cell procedures to treat cardiac patients, the authors showed that the studies reporting the most positive effects also had the highest number of discrepancies in their results. Bearing these uncertainties and discrepancies in mind, our article presents the rationales given by people with serious heart disease for participating in experimental stem cell trials.

AGREEING TO TAKE PART IN A CLINICAL TRIAL

The patients in our study showed great confidence in medicine from the start of their participation in the protocol.

I really believe in it. I'm convinced this is the science of the future. I think we'll all be able to heal ourselves with this. Right now they're working on specific diseases, but maybe one day they'll be able to cure cancer with this. Anything's possible. I believe this is just the beginning. (Patient 10)

The interviews showed that most patients, with a few exceptions, were not aware of this technology before participating in the protocol. The patients generally stated they were keen to participate, as the following account shows:

I had one chance in two of getting better afterwards. Those seemed like good odds to me. I made my decision as soon as he told me about it, without hesitation. (Patient 10)

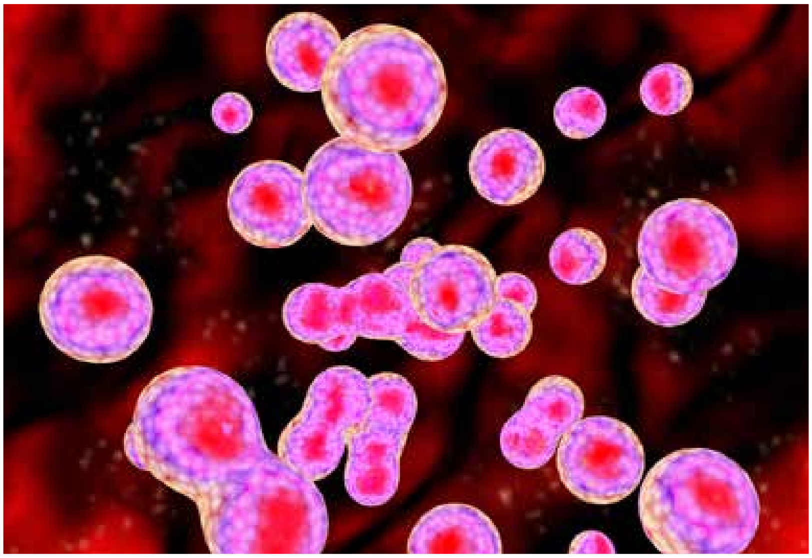
Most of the participants obtained information about the procedure from the consent form. None mentioned using the Internet. Some asked family members or acquaintances to help them decide whether or not to participate in the protocol. The daughter of one patient worked in the medical field and the neighbour of another had successfully participated in a similar clinical trial.

The clinical researchers involved in the trials told us that almost all the patients agreed to participate. The interviews revealed three reasons for this positive response: 1) the apparent simplicity of the process; 2) the absence of ethical issues associated with their participation (compared to embryonic stem cell procedures); 3) the fact that no foreign tissue or substance would be introduced into the patient's body. This resolved the problem of immunosuppression and minimized potential concerns related to identity, contamination and pollution—what Waldby and Mitchell term transcorporeality[4]. One of the researchers interviewed noted:

. . . when the doctor is trying to convince a patient and says "No, no, that's not a stem cell. A stem cell, [that's] you, in your own body, in your bones, that's a stem cell, and we're going to take it out, and put it back into you." So, after you say that, they will say, "No problem at all." Most people would say that. (Researcher B, 2011)

Another motivation was the hope this innovative procedure gave to a person suffering from a potentially fatal disease. It was literally a "technology of hope"[5]:

So, I mean, I knew it was for the good, not for the bad. So I said, "Why not? I'm in this >



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position right now; what do I have to lose?" So I said, "Yeah." The next day there was an ambulance downstairs and—zoom!—they took me in. (Patient 8)

In addition, as noted in the literature, the operation is without major risks for the patient. Patients got the same message from the medical staff who recruited them to participate in these clinical trials:

There was no mention of anything, no complication, danger or things like that. If there was, I wasn't told. There was more positive than there was negative, you know. So the danger was 2% and the rest was 98%. I think it's worth it; even 5% or 10%, it's still worth it. (Patient 8)

Only some patients expressed doubts about the validity of this type of surgery. They were not sceptical about the procedure itself, but rather about the health care system. The following patient believed the hospital was developing a bone marrow bank, like certain establishments that run their own blood banks—but without patients' consent:

They had to take a bone marrow sample and I thought it was to create a bank for themselves, because a lot of people are suffering and need bone marrow. (Patient 4)

The inclusion of ongoing care in the research protocols, such as regular post-operative follow-up care for two years, was another incentive for patients to agree to participate in the trial before meeting with the medical team and surgeon. Their participation in the study would ensure long-term follow-up care and an availability of resources in the health care system that is rarely seen in other departments, and is certainly not the norm for the general public. This argument came more from loved ones and others who influenced the patient's decision.

"My brother said, 'Claude, do it!' You'll get much better follow-up care than if you don't.'" (Patient 6)

This extensive, personalized care undeniably eased patients' concerns. Although the participants rarely used the emergency services offered through the protocol, the fact that these services were available reassured them and gave them a feeling of security, which probably influenced their post-operative health, regardless of whether or not they received a transplant. Paradoxically, this enthusiasm contrasts with their very infrequent visits to hospitals and other health care establishments prior to their heart attack.

THE FIGURE OF THE DOCTOR

Many patients saw their surgeon as a charismatic star, a saviour and an expert. At the same time, some patients reported not seeing their surgeon often on account of his importance, status and many responsibilities. This confirmed his skill and reinforced patients' confidence in his abilities. Their confidence in the protocol and stem cell therapy was therefore linked to their faith in medicine and the professionalism of its representatives.

When your back is up against they wall and they offer you things . . . They're the doctors, not me. I used to be a *mechanic, so I know if something needs to be repaired right away or not. But you're the doctor. You know what you're talking about. I'll just follow what you say.* (Patient 2).

ADVANCING SCIENCE

Patients' confidence in the protocol, medicine and science in general was bolstered by their feeling that they were pioneers helping to advance science. Some patients noted that they were contributing to something bigger than themselves:

It's a new study. I'm a firm believer in research. If people hadn't done experiments with Aspirin, we wouldn't be where we are today. By participating, I can make a small contribution to this research. (Patient 10)

Another patient confided that his participation in the clinical trial had been the most important event of his life.

FROM INDESTRUCTIBILITY TO VULNERABILITY

COMING TO TERMS WITH THE ILLNESS TRAJECTORY

The trajectory of chronic heart disease starts with a heart attack which, for most patients, came as an unexpected, unpredictable shock with no warning signs. It marks the start of a sometimes painful awareness of another body, a "sick" body. That is why patients develop hypotheses around the possible causes of their heart attack. For example, some interviewees pointed to stress and "having too much on the go" as a major cause. Another patient thought he was "invincible" before his heart attack. The men in our sample were, for the most part, former casual workers, labourers and factory employees who were proud of their ability to carry out demanding manual work. After their heart attack, they found themselves forced to adopt an attitude of "care of the self," in Michel Foucault's terms[6], and to see their body in a new light. The trajectory of their disease involved looking back on their past and their attitude towards physical activity and productivity.

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Using the metaphor of a machine allowed them to see their heart attack as a mechanical breakdown and the operation as a repair job. Machines have a limited life span and can stop working if they are not properly maintained.

There was no reason for my heart to give out. I don't know why it happened. But it doesn't bother me too much. If it wasn't my heart, it would be something else. At a certain point, the machine just doesn't work anymore. (Patient 6)

POST-OPERATIVE REPORTS: ACTIVITY AS A SIGN OF A REGENERATED MALE BODY

Although patients knew they would not necessarily be getting a stem cell transplant during their participation in the clinical trial, the vast majority believed that they had indeed been transplanted. The conclusion for most interviewees was "I feel good, therefore I got a transplant":

As long as I feel good and have a lot of energy, I won't lose any sleep over whether or not I got the transplant. I think I probably did, because you don't feel better just like that—unless I wanted so badly to get better that I really believed the placebo was my stem cells. (Patient 10)

Some patients experienced improved health in the medium term, and felt more physically independent than before their heart attack. The following excerpt clearly illustrates how intensely one patient enjoyed carrying out his former activities:

I work 10 hours a day, every day, no problem. I think I feel even better than before my heart attack. I'm not afraid of challenges and I stay fit. I'm still working 70 hours a week. (Patient 10)

However, for the vast majority, post-operative rehabilitation involved getting used to "not being able to do anything anymore," especially when the patient was used to being very active on the job or at home:

For me, there's no middle ground. So I've learned to slow down, but sometimes when I slow down too much, that's not good . . . I don't do anything. (Patient 7)

Some patients became depressed immediately after the operation because of changes in their lifestyle and physical capabilities. One had to stop working in the freight transportation industry, while another found himself unable to open a jar of food:

I was feeling pretty depressed for a while. I couldn't open a jar of peanut butter! I wondered what was going to happen. (Patient 4)

Other participants kept up their previous activities, but adjusted them according to the limitations of their no longer indestructible body. A lack of bodily awareness was replaced by a search for balance:

It didn't change my pace of life, because I still do the same things. I still work just as hard as before, but not as fast. I'm still in construction. Before it would have taken me six hours to raise a platform; now it takes me three days. I get tired, so I sit down and take a break. I don't run like I used to. (Patient 5)

Mowing the lawn, preparing for trips to the cottage or vacations in Florida, and doing jobs around the house were all stereotypically masculine roles:

I still shovel the snow. I asked Dr. N. about it, because everyone was telling me not to do it anymore. (Patient 6)

CONCLUSION

The accounts of the men we interviewed showed huge confidence in the experimental stem cell procedure. The authority of the surgeon and his team, as well as the apparent simplicity and safety of the procedure, eased any uncertainties associated with the protocol. The accounts presented a desire not only to regenerate the damaged organ, but also to rebuild a masculine identity closely intertwined with physical activity and work.

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