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Firefighter willingness to participate in a stem cell clinical trial for burns: A mixed methods study

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ABSTRACT

Adult stem cells represent a potentially renewable and autologous source of cells to regenerate skin and improve wound healing. Firefighters are at risk of sustaining a burn and potentially benefiting from a split thickness skin graft (STSG). This mixed methods study examined firefighter willingness to participate in a future stem cell clinical trial, outcome priorities and factors associated with this decision.

Methods: A sequential explanatory mixed methods design was used. The quantitative phase (online questionnaire) was followed by the qualitative phase (semi-structured interviews). A sample of 149 firefighters completed the online survey, and a purposeful sample of 15 firefighters was interviewed.

Results: A majority (74%) reported they would participate in a future stem cell clinical trial if they experienced burn benefiting from STSG. Hypothetical concerns related to receiving a STSG were pain, itch, scarring/redness and skin durability. Participants indicated willingness to undergo stem cell therapy if the risk of no improvement was 43% or less. Risk tolerance was predicted by perceived social support and having children. Interviews revealed four main themes: a desire to help others, improving clinical outcomes, trusting relationships, and a belief in scientific investigation. Many participants admitted lacking sufficient knowledge to make an informed decision regarding stem cell therapies.

Conclusions: Firefighters indicated they were largely willing to participate in a stem cell clinical trial but also indicated a lack of knowledge upon which to make a decision. Public education of the role of stem cells in STSG will be increasingly important as clinical trials are developed.

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1. Introduction

Over six million people per year suffer burns, resulting in permanent disfigurement, disability and psychological trauma [1–3]. Fifty nine percent of all burns occur among the unemployed and 23–42% among the employed [1]. Welders, cooks, laborers, food service workers and mechanics are at higher risk of burn than other occupations [4–6]. Burns account for 8–25% of all work-related injuries in firefighters [7–10] and those at the nozzleman position are at greatest risk [11].

The most common treatment for deep burn injury is split thickness skin graft (STSG) surgery [12]. Although this procedure is sufficient to close the wound, it does not look or function like normal skin because it lacks dermal appendages. Consequently patients suffer chronic pain, itch, hypersensitivity, recurrent wounds and psychosocial issues [13–15]. Patients may receive lifelong care and multiple reconstructive surgeries associated with significant anxiety, depression, pain and appearance-related distress [16,17].

There is the potential to use a cell-based therapy to improve the functional outcome of STSG. Dermal stem cells reside within the hair follicle mesenchyme, where they self-renew and generate differentiated progeny that maintain the mesenchymal cells that comprise the hair follicle (dermal papilla and connective tissue sheath) and function to induce cyclic regeneration of hair follicles throughout life [18]. These cells can be isolated *in vitro* where they form self-renewing colonies referred to as skin-derived precursors or ''SKPs'' [19–21] and can be transplanted into full-thickness skin wounds where they form new dermal tissue [21]. In thinking about designing future clinical trials that utilize a stem cell transplant-based approach, we wanted to gain insight into how willing *potential* patients might be to receive such a therapy. We were particularly interested in how risk and STSG clinical outcomes might influence their overall willingness to participate.

Measures of willingness to participate in a clinical trial and STSG-specific measures of risk were modeled after a paper in the field of spinal cord injury [22]. Overall risk tolerance was conceptualized based on the health utility literature. Additional measures were chosen based on determined or hypothesized association with risk. Past research has determined that Caucasians, those with lower education, and women are more risk averse [23]. Furthermore, the evidence is mixed regarding the impact of age on risk tolerance with some reporting younger individuals are more risk tolerant [24] and others indicating risk tolerance is higher in older individuals [25]. Personality has consistently been found to be associated with risk tolerance. Using the Big Five factor theory of personality traits [26], some have determined those high in openness and agreeableness are more likely to make risky judgments [27,28] and others have determined higher extraversion and openness and lower neuroticism, agreeableness, and conscientiousness are associated with increased risk [29].

The primary objective of this mixed methods study was to determine whether firefighters, a population at risk of sustaining a burn and therefore potentially undergoing a STSG, would be willing to participate in a future stem cell clinical trial. Furthermore, risk tolerance to specific risks associated with stem cell therapy and motivations for pursing stem cell therapy were also explored. It was expected that a stem cell specific risk measure (i.e., a standard gamble) would be positively associated with a willingness to participate in stem cell therapy Likert-type item (H1) and that gender, age, presence of dependents, perceived social support, and personality (specifically openness) would predict risk tolerance (H2). It was expected that men, younger individuals, those without children, those who perceived less social support, and those high in openness would be more risk tolerant. Qualitative interviews aimed to gain a greater understanding of the concept of risk as experienced by firefighters and how this may influence their decision to participate in future clinical trials.

2. Methods

The Conjoint Health Research Ethics Board at the University of Calgary granted ethics approval and all participants provided informed consent. Participants were provided with a list of local resources for psychological support in the event that the study generated participant distress. The study used a sequential explanatory mixed methods design where a quantitative phase (an online survey) is followed by a qualitative phase (semi-structured interviews), to gain a better understanding of the quantitative results [30]. The qualitative data was used to assist in explaining, interpreting [31] and completing [32] the descriptive quantitative data. This design provides a better answer to the research questions than either method alone.

3. Samples

Two samples were recruited to examine firefighting risk. All participants had to be 18 years of age or older and either retired or employed professional firefighters in order to participate. Firefighters who had received a STSG in the past were excluded as we were interested in a pre-surgical sample. For the quantitative phase participants were recruited from a firefighters union in Calgary, Alberta. The union executive distributed study invitations, the survey link, and reminder emails to 1053 firefighter email addresses. Participation in the survey was anonymous. The questionnaire was distributed using a secure, cloud-based software [33] and included the following measures in the order presented below. As there was no literature upon which to base an expected effect size, a sample size calculation was run based on H2 to determine the sample size required to detect a medium effect ($f^2 = 0.15$). With seven predictors ($1 - \beta = .8$; $\alpha = .05$) 103 participants were required [34].

In the qualitative phase, one of the authors (PH) gave a short recruitment presentation at the 2015 Firefighter Special Interest Group American Burn Association (ABA) Conference in Chicago, USA, describing her interest in the risk practices of firefighter work. All firefighters in attendance were invited and fifteen agreed to participate.

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