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Outcomes important to burns patients during scar management and how they compare to the concepts captured in burn-specific patient reported outcome measures

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ARTICLE INFO

Article history:
Accepted 15 September 2017
Available online xxx

Keywords:
Burn scar management
Patient-reported outcomes
Qualitative research
Interviews

ABSTRACT

Background: Pressure garment therapy (PGT) is an established treatment for the prevention and treatment of hypertrophic scarring; however, there is limited evidence for its effectiveness. Burn survivors often experience multiple issues many of which are not adequately captured in current PGT trial measures. To assess the effectiveness of PGT it is important to understand what outcomes matter to patients and to consider whether patient-reported outcome measures (PROMs) can be used to ascertain the effect of treatments on patients' health-related quality of life. This study aimed to (a) understand the priorities and perspectives of adult burns patients and the parents of burns patients who have experienced PGT via in-depth qualitative data, and (b) compare these with the concepts captured within burn-specific PROMs.

Methods: We undertook 40 semi-structured interviews with adults and parents of paediatric and adolescent burns patients who had experienced PGT to explore their priorities and perspectives on scar management. Interviews were audio-recorded, transcribed and thematically analysed. The outcomes interpreted within the interview data were then mapped against the concepts captured within burn-specific PROMs currently in the literature.

Results: Eight core outcome domains were identified as important to adult patients and parents: (1) scar characteristics and appearance, (2) movement and function, (3) scar sensation, (4) psychological distress, adjustments and a sense of normality, (5) body image and confidence, (6) engagement in activities, (7) impact on relationships, and (8) treatment burden.

Conclusions: The outcome domains presented reflect a complex holistic patient experience of scar management and treatments such as PGT. Some currently available PROMs do capture

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https://doi.org/10.1016/j.burns.2017.09.004

the concepts described here, although none assess psychological adjustments and attainment of a sense of normality following burn injury. The routine use of PROMs that represent patient experience and their relative contribution to trial outcome assessment versus clinical measures is now a matter for further research and debate.

1. Introduction

Pressure garment therapy (PGT) is an established and widely used treatment for the prevention and treatment of hypertrophic scarring in burns [1–3]; however, at present there is limited evidence of its effectiveness and cost-effectiveness. Systematic reviews demonstrate a small but statistically significant effect of PGT on scar height, compared to no PGT, but no significant effect on global scar scales or other measures of scar characteristics such as pigmentation, vascularity, pliability and colour [4,5]. Survivors of burn injuries often experience a range of problems including: scar cosmesis; reduced function; psychological and social issues, and reduced overall quality of life (QoL) [6]. These multi-factorial problems can reportedly impact appearance; interpersonal relationships; emotional, social, sexual, and physical functioning of burns patients [7,8]. Whilst the evidence for PGT is limited, measures that feature in systematic reviews and underlying studies do not necessarily reflect these multifactorial issues, and may not adequately represent the views and priorities of patients. To appropriately assess the effectiveness of PGT it is therefore necessary to (i) understand what outcomes matter to patients and (ii) to consider whether patient-reported outcome measures (PROMs) such as measures of health-related quality of life (HRQoL) and symptoms may be used to ascertain the effect of treatments on patients' multifactorial concerns. Bredart et al. [9] highlight the importance of using qualitative data collection methods in the development of PROMs to help elicit items that reflect the experience of the specific population of interest. Griffiths et al. [10] have stressed the need for PROMs in burns to represent the key outcome domains that are important to patients' specific and unique experiences of burn injury. Our aims were therefore to (a) understand the priorities and perspectives of adult burns patients and the parents of paediatric and adolescent burns patients who have experience of PGT via in-depth qualitative data, and (b) compare these with the concepts captured within burn-specific PROMs.

2. Materials and methods

2.1. Study design

This qualitative research, informed by interpretive description [11], formed part of a wider mixed-methods feasibility study of PGT for the prevention of abnormal scarring after burn injury in adults and children (the PEGASUS study) [12,13]. The overall aim of the PEGASUS study was to assess the feasibility of a full-scale randomised controlled trial (RCT) on the effectiveness and cost-effectiveness of PGT. Whilst the qualitative research nested within PEGASUS was broad-ranging, one key objective was to reflect on the conceptual content of outcome measures that might be used in a future RCT of PGT.

2.2. Eligibility, sampling and recruitment

Potential participants were deemed eligible for interview if they were (i) adults or (ii) parents/carers (referred to as parents from this point) of paediatric (0–8 years) and adolescent (9–15 years) burns patients who had had at least six months' experience of PGT and had finished PGT no more than two years prior to data collection. We recruited a diverse range of participants according to their sex, age, ethnicity, type and severity of burn to facilitate a maximum variation sample. Participants were recruited by occupational therapists (OTs) and/or research nurses (RNs) in four of the PEGASUS pilot trial sites across England: Queen Elizabeth Hospital, Birmingham (adults only); Birmingham Children's Hospital (parents only); St Andrews Centre for Plastic Surgery and Burns, Broomfield Hospital, Essex (adults only); and Queen Victoria Hospital, East Grinstead (adults and parents). Clinical staff provided information sheets to potential interviewees and took written consent to pass contact details on to the PEGASUS qualitative research team. A member of the qualitative research team then contacted potential interviewees, provided further information and answered questions as necessary, before arranging a suitable time, date and venue for the interview. Written informed consent was provided by all participants prior to the start of data collection.

2.3. Ethics

A favourable opinion for the PEGASUS study was received from the West Midlands: Coventry and Warwickshire Research Ethics Committee (14/WM/0160).

2.4. Data collection

Semi-structured interviews were identified as an appropriate data collection method given that they facilitate an in-depth exploration of participant views [14] and are particularly useful in discussions of sensitive or traumatic experiences. Interviews were conducted by a trained non-clinical qualitative researcher who was independent of the participant's/their child's clinical care team. Interviews were mainly conducted in the patient's home, which was the preferred venue; although a small number took place via telephone. A semi-structured discussion guide informed by the literature, discussions with our patient and public involvement (PPI) group, and the wider PEGASUS research team guided data collection. The interviews were conducted in a participant-focused manner allowing issues and perspectives important to participants to emerge naturally [15]. Topics discussed included: accounts of the

Please cite this article in press as: L.L. Jones, et al., Outcomes important to burns patients during scar management and how they compare to the concepts captured in burn-specific patient reported outcome measures, Burns (2017), https://doi.org/10.1016/j.burns.2017.09.004