INTRODUCTION

The international prevalence of diabetes was estimated at 194 million people in 2003 (Atkins et al, 2006, p.1). Within Australia, the prevalence of diabetes is 7.4 per cent of the national population with ten per cent of all Australian cases of diabetes being Type One Diabetes Mellitus (T1DM) (Atkins et al, 2006, p.5), (Atkins et al, 2006, p.3). Craig et al (2005) over a 13 year study period found that the national incidence of T1DM increased at a rate of 16.4 per cent between the years 1990 and 2002. Life expectancy is currently shortened by 15 years by virtue of the diagnosis (Australian Government Department of Health and Ageing, 2006, p.1). The National Diabetes Register revealed that 24.6 out of 100,000 Australian children aged 0-14 years are diagnosed with T1DM per year and the incidence in toddlers and preschool-aged children has increased over the last decade (Ahern et al, 2004, p.1601; AIHW, 2006, p.1).

In 2007 in Australian there were 8, 500 children with diabetes and this figure is rising; 7,500 do not have access to Continuous Subcutaneous Insulin Infusion Therapy (CSII) (Diabetes Australia, 2007, p.27). Consequently, the Australian National Priorities research advocates increased access to CSII for paediatric presentations aged 0-18 years (Diabetes Australia, 2007, p.26). Therefore sufficient evidence is required to communicate an holistic picture of the benefits and harms of CSII for prudent clinical and patient decision-making, especially for practice nurses and those nurses who hold diabetic education credentials (Diabetes Australia, 2007, p.27).

The National Diabetes Strategy highlights the necessity of interventions that focus on improving quality of life whilst minimising complications associated with the chronicity of the disease (Atkins et al, 2006, p.2). CSII may play a significant role in this pursuit (Atkins et al, 2006; Carpenter et al, 2001).

Quality of Life

Current nursing practice acknowledges the impact of disease on the whole person as a contextualised entity and addresses the unique and dynamic nature of the individual. Quality of life is conceptualised as the degree to which patients’ lives contain positive features they deem significant to themselves and that the impact of disease is minimised. Positive features include gratification with lifestyle, social participation, self-fulfilment and emotional satisfaction (Shaw & Speight, 2007, p.693). When discussing quality of life, researchers include themes of patient treatment satisfaction, disease-related worries and perceived control, and lifestyle flexibility (Airey et al., 2004, p.95; Ahern et al., 2004; Shaw & Speight, 2007). Mindful of the contemporary state of diabetes globally, this paper assesses the impact of CSII on quality of life for paediatric patients with T1DM.

SEARCH STRATEGY

The databases CINAHL, ProQuest Nursing and Allied Health Source, The Joanna Briggs, MEDLINE and Ovid Databases, and The Cochrane Library were searched, allied with supplementary desktop research of the journals Diabetes Spectrum and Diabetes.

The search terms used for all databases were:
1. Type 1 Diabetes OR Juvenile Diabetes
2. Continuous Subcutaneous Insulin Infusion OR Insulin Pump
3. Paediatric OR Adolescent OR Child
4. Quality of Life OR Lifestyle OR Psychosocial
5. 1 AND 2 AND 3 AND 4

Seventy-eight studies were identified via database and hand searching. Twenty were deemed relevant for evaluation based on citation and abstract analysis. Inclusion criteria were based on relevance to the aim of this critical review, suitability of the design to stated aims, and publication during or after 2003. Both international and Australian research was included. Reviews and primary research articles were included, and letters and discussion papers were excluded (Blunden et al., 2000; Burns & Grove, 2005).

Seven articles were considered appropriate for the review. One study is Australian, one Israeli, one British, and four are North American. There is one randomised controlled trial; one randomised open crossover trial, one systematic review, one prospective quantitative study, two descriptive observational surveys, and one descriptive study.

RESULTS

The seven research articles reviewed highlight themes concerning the effects of CSII use on the quality of life of patient, parent and family in the management of paediatric T1DM. There are concerns about diabetes, treatment satisfaction, the impact of diabetes, self-efficacy, lifestyle flexibility, psychosocial challenges and overall quality of life. Each theme will be addressed in turn.

Concerns About and Impact of Diabetes

Grey et al (2005) conducted an uncontrolled observational prospective study of paediatric patients aged ten to 19.6 years, to assess the impact of CSII use on quality of life. Children were recruited from a paediatric diabetes referral and treatment centre in Western Australia. A modified version of the standardised Diabetes Quality of Life Instrument (DQOL) targeted to youth and the Self-Efficacy for Diabetes Scale (SED) (Airey et al., 2005, p.95), were used to assess quality of life, including worries about diabetes. The written questionnaires were completed prior to testing and again after six months of CSII use by 43 respondents. There was no statistically significant alteration in concerns about diabetes post-CSII use, however, a decline in the impact of diabetes on participants’ lives after initiation of CSII was identified (Airey et al., 2005, p.95). Due to the uncontrolled nature of this quantitative study, including the response rate and sample size, the ability to generalise from these findings is limited (Airey et al., 2005, p.95-96).

Grey, Knaf, Sullivan-Bolyai and Tamborlane (2004) conducted a descriptive qualitative study which described the experiences of parents managing their young children’s T1DM using CSII. Parents of children less than 12 years old with T1DM who were managed with CSII were interviewed. Twenty-one interviews were conducted with parents of 16 children by a trained research assistant at a location of the participants’ convenience. Using open-ended questions, the interviews lasted between 90 and 230 minutes. Extraneous variables of culture, marital status and education level were also taken into account.

Grey et al (2004) found CSII therapy produced significant work and stress for parents and their children. One respondent captured this by saying “The pump is not a free ride; it still takes work to manage…” (Grey et al, 2004, p.319). However, a majority of participants conveyed that it became easier to remove constant thoughts of diabetes from their minds. All participants said the benefits of CSII far outweighed the work, and that worry and stress about overall diabetes care were reduced within the family. As one interviewee stated:

It [diabetes] is only part of my life now, and it used to be my whole life. (Grey et al, 2004, p.320)

Cogen, Mednick and Streisand (2004) used a grounded theory qualitative descriptive design and a quantitative questionnaire to describe the satisfaction of parents and children with transition to CSII and ensuing quality of life. Twenty-two children between the ages 10 and 18, and one parent each were recruited from an urban United States children’s hospital. The Insulin Pump Satisfaction Questionnaire (IPTSQ) was designed and implemented by the authors to assess treatment satisfaction. The Diabetes Quality of Life for Youths (DQOL-Y) questionnaire was used to measure quality of life indicators. Both questionnaires were tested for validity. Results indicate that 73 per cent of parents and 81 per cent of children reported fewer diabetes related worries (Cogen et al, 2004, p.175). The research design enhanced auditability, though no triangulation was evident (Burns & Grove, 2005).

Bucklo et al (2005) performed a randomised controlled trial to study the effects of CSII on diabetes control and family life in children with T1DM aged one to six years. Participants had a disease history of at least six months. Twenty-six children were randomly placed into a continuing treatment group and a CSII group for six months. The therapies of continuing treatment were not defined and may affect external validity in design construct (Elliot et al, 2003, p.269). Quality of life and
family dynamics were assessed via a validated questionnaire prior to as a baseline and after six months of treatment.

The authors found that although mothers in the continuing therapy group reported greater impact of diabetes and more parental stress than the CSII group prior to the start of the trial, there were no statistically significant differences in the impact of diabetes on quality of life between the two groups after six months. This pattern was repeated in the case of fathers in relation to psychological distress (p.1279-1280).

**Treatment Satisfaction**

Cogen et al (2004) found that individuals who were more satisfied with their treatment were also more satisfied with life. In contrast Airey et al (2004) found that there was no alteration in satisfaction with life despite the change in treatment regimen to CSII.

Benzaquen et al (2003) performed a randomised control trial to compare the effectiveness and practicability of CSII compared to multiple daily injections of insulin in paediatrics. Twenty-three patients aged nine to 14 years were followed for six months. The Diabetes Treatment Satisfaction Questionnaire (DTSQ) and DQOL-Y were completed prior to commencement of the study and at the end of each phase. Benzaquen et al (2003) found that there was no statistically significant difference between the DTSQ scores of the CSII group and that of the multiple daily injections of insulin groups in either phase. This indicates that the management style was distinct from treatment satisfaction (Benzaquen et al, 2003, p.562). Despite these findings, 16 of the 23 subjects chose to remain with CSII therapy, indicating a treatment preference by a majority of the participants (Benzaquen et al, 2003, p.562).

The reliability of these findings is questionable as the subjects received increased educational and professional support 24 hours per day with detailed management strategies. Thus the effect of being studied may have impacted results as intensive support may have accounted for the quality of life indicators, independent of the type of treatment provided. There was also potential for bias as the authors received funding from a company that manufactures CSII devices (Benzaquen et al, 2003, p.562).

**Self-Efficacy**

Self-efficacy is the ability of patients to self-manage and to feel in control of their condition and treatment. Airey et al (2005) found the score for self efficacy increased significantly with the use of CSII as measured by the Self-Efficacy for Diabetes Scale (SED) questionnaire largely due to increased independence. Cogen et al (2004) also found that 36 per cent of parents questioned reported use of CSII meant that their children were more capable of managing their diabetes themselves (p.175).

Qualitative interview responses collated by Grey et al (2004) revealed that some children became more actively involved in their care once initiating CSII. This was encapsulated by one parent’s statement that their child had “…become very confident in his abilities to take care of his diabetes” (Grey et al, 2004, p.520). The results are limited by the sample which was racially and educationally homogenous and only individuals who continued to use CSII were interviewed (Elliot et al, 2003, p.149).

**Lifestyle, Freedom and Flexibility**

Grey et al (2004) identified that school-aged children generally viewed CSII as a “freedom reward” (p.319). Parents stated that they “no longer had to be on a schedule” and that CSII afforded their children more freedom in terms of eating, sleeping and activities (Grey et al, 2004, p.321). This flexibility benefited the entire family in all aspects of daily life (Grey et al, 2004, p.320).

Cogen et al (2004) found 81 per cent of children and 73 per cent of parents surveyed indicated improved flexibility with CSII use and nine per cent of parents reported lifestyle benefits (p.175). Parents and children tended to focus on lifestyle improvements rather than metabolic control as benefits of CSII therapy. The results of qualitative questioning revealed positive changes in flexible eating and food variety. Diet restrictions could be weakened to a degree, rigid eating schedules did not need to be followed and children could sleep throughout the night without rising to check and respond to sugar levels.

**Overall Quality of Life**

Delamater et al (2006) performed a survey of children and their parents at two North American diabetes clinics to compare health-related quality of life between children using CSII and users of multiple daily injections of insulin. One hundred and sixty children and adolescents aged five to 17 were included with their main carer. Strict inclusion criteria assisted in minimising the effects of being studied. Health-related quality of life was assessed using the Paediatric Quality of Life (PedsQ) questionnaire. Delamater et al (2006) found no statistically significant difference in quality of life between users of multiple daily injections of insulin and CSII users. The survey found older children reported a higher quality of life score than younger children, however younger children reported better disease-specific health-related quality of life (Delamater et al, 2006, p.655).

British authors Barnard, Lloyd & Skinner (2007) completed a systematic review of published literature addressing whether CSII improves quality of life. Seven paediatric studies where identified through clear an audit trail involving electronic database and published reference searching. Barnard et al (2007) found existing research was limited, conflicting and often ambiguous. Further, a majority of studies contained numerous methodological design flaws, such as inclusion criteria, uncontrolled extraneous variables, lack of control groups and incomparability. Of the three randomised control trials identified, Barnard et al (2007) found that only two reported an increase in quality of life. Barnard et al (2007) concluded that it was difficult to provide definitive results based on available research.

Parent interviews undertaken by Grey et al (2004) found an overall increase in quality of life for parents, children and the family as a whole with use of CSII therapy. This improvement centred on increased flexibility regarding eating times, food selection and sleeping; and glycaemic control.

Cogen et al (2004) found parents and children experienced positive changes with CSII use. This improvement centred on enhanced flexibility and lifestyle (p.175). Conversely, Benzaquen et al (2002) found no statistically significant difference between multiple daily injections of insulin and CSII treatment groups in terms of quality of life.
DISCUSSION

Quantitative research in this area contains flaws as in some cases the strict criteria of the design were not met. Studies undertaken by Benzaquen et al (2003), Buckloh et al (2005), and Delamater (2006) contain a degree of bias (such as sampling errors). Further, Benzaquen et al (2003) did not document procedures for internal reliability and validity. The small sample sizes of research undertaken by Benzaquen et al (2005), Buckloh et al (2005) and Cogen et al (2004) mean that the results are limited.

Some studies, such as Cogen, Mednick and Streisand (2004) attempted to incorporate elements of both qualitative and quantitative methodology into their design which proved burdensome and conflicting. Methodology from the two designs are antithetical as qualitative research values the human experience whereas quantitative focuses on that which can be statistically measured.

From the research reviewed in this paper, qualitative designs appeared to be contextually appropriate and enhanced clinical knowledge. Patients’ and their families’ preferences and realisations regarding what was beneficial or detrimental to their quality of life are explicated (Barnard et al, 2007; Grey et al, 2004). However, researchers used varying definitions of quality of life and did not always identify the same key indicators of quality of life despite thematic links.

The variety of research designs implemented for information gathering makes meaningful comparison challenging, and potentially flawed. This results from competing objectives, measures and mechanisms for data analysis. However, varied focus and design provide a diverse range of perspectives on the topic. Conflicting results within the evidence are also apparent. The notion that CSII promotes key improvements in flexibility of lifestyle, especially in regard to eating and sleeping, and increased satisfaction with the treatment regimen are supported by all reviewed researchers although disputed by Benzaquen et al (2003) and questioned by Barnard et al (2007) and Buckloh et al (2005).

Most authors concluded that, based on their research making a determination about the positive or otherwise impacts of CSII on quality of life was difficult to do definitively. As the only example of level one evidence, the systematic review conducted by Barnard et al (2007) found poor quality research design accounted for the lack of evidence, rather than there not being quality of life improvement. Similarly, Airey et al (2005) highlighted that while their quantitative research demonstrated no quality of life improvement, qualitative anecdotal responses from clients were not commensurate with this finding.

IMPLICATIONS FOR CLINICAL PRACTICE

It is incumbent on nurses, especially practice nurses and diabetic educators, to be aware of the potential and realised fears of parents and children regarding CSII use. Research highlights that education is pivotal to alleviate the negative aspects of the therapy. Diabetes ‘re-education’ is advocated to manage novel issues that arise with continued CSII therapy (Cogen et al, 2004). Grey et al (2004) revealed that some participants found manufacturer’s informational videos misleading. Therefore clinicians in the area may wish to promote development of appropriate education packages and user feedback for improved outcomes.

CSII as a safe and effective diabetes treatment option is supported by the reviewed research. Advocacy for increased accessibility and prescription is prudent (Diabetes Australia, 2007; Keen & Pickup, 2001). As Cogen et al (2004) found, glycaemic control may not always be the impetus for CSII initiation. Rather, CSII may be promoted for patients with psychosocial issues with their current regimen (p.180). Nurses may cite improvements in lifestyle as a primary benefit of CSII when discussing the option with families. Such issues should be addressed in preparing prospective users (Cogen et al, 2004, p.181).

IMPLICATIONS FOR FUTURE RESEARCH

Further research is necessary in the area of quality of life related to the use of CSII for the management of children with T1DM. Such research should address the incongruity in quality of life definitions among researchers and subsequent assessment tools for improved comparability of the findings. Clear research objectives need to be outlined as current research is too broad to collate findings comprehensively. Researchers need to identify what children with T1DM perceive as important in their treatment and how it fits into their lives. This idea of patients determining important issues is fundamental to the paradigm of quality of life and patient-centred nursing care. Longitudinal studies looking at the relationship between glycaemic control and quality of life may be prudent as some research suggests that this could account for the improvements in quality of life (Benzaquen et al, 2003; Delamater et al, 2006). Research focusing on those initiating CSII at the time of diagnosis in comparison to those commencing CSII as an alternative to multiple daily injections of insulin would enhance design control and hence the implications clinicians may derive from results (Cogen et al, 2004, p.175).

CONCLUSION

Due to the chronicity of the diabetes and its impact on lifestyle an holistic approach to diabetes care is required. As such, quality of life issues are central to prudent and patient-centred nursing care (Barnard et al, 2007; Cogen et al, 2004; Grey et al, 2004). From the evidence reviewed the question of CSII positively impacts quality of life for paediatric T1DM patients cannot be answered with authority. Further research is required to provide evidence for clinicians in promoting CSII therapy for children and their families. However, the current state of evidence suggests that improved lifestyle, increased flexibility with meal times, food selection, sleeping, and heightened self-efficacy are probable benefits of CSII use for children and their families.

References


Shaw, J., & Speight, J. (2007). Does one size really fit all? Only by considering individual preference and priorities will the true impact of insulin pump on quality of life be determined. Diabetic Medicine, 24, 693-695.