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Quality-adjusted life years gained in patients aged over 65 years after total hip replacement

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Summary  
Background: Total hip replacement (THR) is an effective, but cost-intensive health care procedure for older people. Because of demographic changes in Western Europe, THR-associated financial investment in health care has become a priority. To provide a quantitative rationale for a discussion within Western European health care systems, we undertook a prospective assessment of the benefit of an additional intervention following THR from the patient’s perspective and as measured by quality-adjusted life years (QALYs).

Aim: To measure the difference in health-related quality of life between an intervention (telephone support) and control group preoperatively and at follow-up 9 months after THR.

Methods: A randomised clinical trial was conducted which allocated 180 patients aged over 65 years to either an intervention group or a control group. The control group received conventional treatment and the intervention group received both
conventional treatment and telephone support after discharge. QALYs were calculated from measures of health-related quality of life using the SF-36 questionnaire. These scores were transformed to QALYs using a formula based on the method developed by Brazier et al. (1998).

Results: Both the control and the intervention patients reported significant changes in health status from preoperative status at 3 and 9 months after surgery. Both groups group had a gain in QALYs.

Interpretation: There was a significant gain in health status in both groups. However, no significant or clinically relevant differences between the two groups were observed at follow-up within this timeframe.

Introduction

In the European Union (EU) member states over 190,000 total hip replacements (THRs) are performed every year. In the Nordic countries some 50,000 THRs are carried out on an annual basis (Health Statistics, 2004). In Denmark, with a population of 5 million people, approximately 20% of the population are over the age of 65 years and the annual incidence of THR among patients aged over 65 years is about 4500 (Hirvonen, 2006).

Osteoarthritis (OA) of the hip is a severe condition that causes pain and reduced physical and social functioning for the individual and imposes an economic burden on society. Compared with the normal population, patients with OA have reduced health-related quality of life and reduced social functioning, especially women, patients living alone and those who are dependent on family support (Hirvonen, 2006; Croft et al., 2002; Ackermann et al., 2005; Bachmeier et al., 2001; Nilsson, 2002; Danish Arthroplasty Registry, 2005).

The most common, and very effective, treatment is surgery for total hip replacement (THR), which reduces pain and improves joint movement and mobility (Croft et al., 2002). The surgical procedure has also proven effective in relieving patients’ pain. Because OA affects middle-aged and older people, the need for THR will increase in future due to an increasing percentage of older people in society.

For some this type of surgery may not improve overall quality of life because an improvement in general health status does not always occur. Patients do expect an overall improvement in all functions of daily life, and not just pain relief and improved walking ability (Södermann et al., 2000; Munk et al., 1988), but a number of studies have shown that some patients live more or less the same life they did before surgery and do not achieve improved living even if they do experience pain relief and improved walking ability (Lieberman et al., 1997; Södermann et al., 2000). Six months after surgery they still experience reduced health status which reduces their ability to travel to take holidays, take part in hobbies and leisure activities and to perform other activities of importance for daily living (Mahomad et al., 2002; Ragab, 2003; Rissanen et al., 1996; Montin et al., 2008).

In previous studies of surgical patients telephone support by a specialist nurse after early discharge reduced readmission to hospital and improved patients’ well-being within the first three months after discharge (Savage, 1999; Powell et al., 2001).

We undertook a simple intervention program involving telephone and professional support conducted by a nurse (Hordam et al., 2008). The intervention involved conducting telephone interviews at 2 and 10 weeks after surgery which aimed to identify patients’ post-operative needs and provide support and counselling specific to individual problems (Hordam et al., 2008).

Both the clinical effectiveness and the economic investment in health care must be considered simultaneously to assist in making funding decisions. The marginal and incremental cost-effectiveness ratio concept (Munk et al., 1988) has
been shown to provide quantitative data which allows easy interpretation and direct comparison with treatment alternatives: The cost-effectiveness ratio relates the costs of an intervention to its benefit from a patient’s perspective, mostly estimated in terms of monetary units gained through quality-adjusted life years (QALYs) (Pedersen et al., 2006). This estimation of the treatment’s effectiveness in terms of gain in QALYs, allows for interpretation of patient-related benefits as well as comparison of cost-effectiveness estimates with alternative treatments (Drummond and McGuire, 2006). In particular, this enables comparison of patient-related benefit with other treatments that have already undergone scrutiny. Providing such transparent data enables resource allocation discussions to take place which enable the economic evaluation of intervention options for older patients with THR (Drummond and McGuire, 2006).

Aim of the study
To compare differences in health-related quality of life expressed in QALYs between patients over the age of 65 receiving conventional treatment after THA with that of patients having conventional treatment and telephone support 2 and 10 weeks after discharge.

Material and methods
Methods
Sample
The study was carried out in two orthopaedic wards at a university hospital in Denmark in the period between January 2005 and May 2007. A total of 180 patients aged 65 and over living in the catchment area for the hospital and consecutively admitted for elective THR in the hospital’s two orthopaedic surgery wards were recruited to the study. In total 175 patients agreed to participate. The age of participants ranged from 65 years to 88 years.

Design
In this randomised controlled trial the patients in the control group received conventional treatment. Patients in the intervention group received the conventional treatment and telephone support. The patients in the intervention group were contacted by phone by a specialist nurse at 2 and 10 weeks after discharge. The effect of the intervention on patients’ health status was assessed. Data on patients’ health status were collected by a postal questionnaire. The questionnaire was sent 4 weeks before planned surgery and then at 3 and 9 months after discharge. If patients did not respond, they received one reminder.

In order to ascertain the sample size a power calculation was conducted based on findings from a cross sectional study (19). We used the physical dimensions of health status as the primary outcome variable. The mean physical score was 49.4 with a standard deviation (SD) of 26.1. Alpha in this study was set to 5% and beta to 20%. We hypothesised that the intervention could lead to an improvement of 50% in the physical health score. When the sample size was calculated, 68 patients were needed in both the intervention group and the control group. With an expected dropout of 22% at least 160 patients were to be recruited to the study.

All patients were recruited from the waiting list and were randomised to an intervention group or control group. We prepared 200 envelopes of which 100 contained a note that referred the patient to either the intervention or the control group. When patients returned their first questionnaire before admission an envelope was opened placing patients in one of the groups. Neither the hospital staff nor the patients were informed of the result of the randomisation before discharge. This process allocated 68 patients to the intervention group and 93 to the control group. Of these 161 patients participated (see Fig. 1).

Telephone counselling
The nursing intervention in this study was based on the model put forth by Salling Larsen (1988). The model is based on Murray and Maslow’s theories of motivation combined with Piaget’s theory of development in which the main goal is to promote and maintain patients’ active involvement in their own care. The model includes the following elements:

(1) Assessing the patient’s normal activities in relation to health and activities of daily living. This assessment was based on Maslow’s motivation hierarchy and Murray’s theory on subjective and objective press for human activities (beta-press and alpha-press).

(2) Continued dialogue between the patient and the nurse to ensure information sharing, teaching and improvement of the individual care.

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(3) Planning of nursing care with reference to the patient’s usual activities of daily living.

(4) Use of the principles embedded in primary nursing.

This model had previously been tested in studies which included patients with various orthopaedic diseases and the findings confirmed that patients cared for using this model experienced more personal activity and growth during a hospital stay compared with patients given standard care (Pedersen, 2005). In our study all of these elements were carried out during the care process within the telephone interviews.

Together the patients and the nurse assessed the patients’ situation and areas of needed. The assessment focused on eight main dimensions which considered the patients’ situation after THR. These were:

(1) Well-being.

(2) Expectations of physical function after surgery.

(3) Expectations of physical function compared with those before surgery.

(4) Symptoms (pain, leg-oedema, vertigo, sleep disturbance, nausea, other concerns).

(5) Problems with eating and appetite.

(6) Fluid intake.

(7) Ability to follow prescribed activity and exercise.

(8) Need of support from family.

For each of the problems identified, individual solutions were suggested and practical counselling was given. The phone counselling was performed by the same nurse on each occasion using a structured interview guide inspired by the findings from Savage (1999).

Health status measurement

The Short Form-36 (SF-36) is a self-administered instrument used to assess overall health status (Bjorner et al., 1998). The instrument has been widely used and shown to be responsive and valid in numerous studies. The wide use of the instrument allows comparison of health status of patients with many different diseases. The instrument is a 36-item questionnaire that assesses health status as it relates to the following eight domains: (1) general health (GH), (2) physical function (PF), (3) role physical (RP), (4) bodily pain (BP), (5) vitality (VT), (6) social functioning (SF), (7) role emotional (RE), (8) mental health (MH)
The instrument is scored as a profile, meaning that separate scores are recorded for each domain, and an overall summary score is not calculated. Raw scores are standardised to a point scale ranging from 0 to 100, with higher scores representing better health status. Domain and summary scale scores can be normalised, using the general Danish population means, so that the average score is 50, and the SD is 10 (Ware and Sherbourne, 1992, Gandek et al., 1998).

Calculation of health-related quality of life

The score obtained on the SF-36 was transformed to a single index of health-related quality of life using the approach described by Brazier et al. (1998, 2002), who found a correspondence between scores of SF-6D and QALY index values. To use this functional relationship, the eight domains of SF-36 had to be transformed to six SF-6D scores which was done by merging RP, RE and GH scores. The remaining six dimensional scores could then be translated using the empirically obtained connection between the two measures.

Ethical considerations

The study (Clinical Trials Registry: NCT00226070) was approved by the local ethics committee and registered with the data protection authorities. Written information was given to all participants, and it was made clear that participation was voluntary. The patients were included after giving their written consent.

Results

At baseline there were no differences between the patients in the intervention or the control groups. The characteristics of the participating patients are given in Table 1. The mean length of stay in hospital for all participants was 6.4 (2.4) days. Before admission 14 patients were excluded because their operation had been cancelled, postponed or changed to another procedure, resulting in 161 patients being enrolled in the study. During the study 39 patients dropped out, 11 (16.4%) patients in the intervention group and 28 (30.1%) in the control group ($p = 0.031$) thus it was possible to follow...
122 (75.7%) of the patients during the entire study time. Among the patients who dropped out the mean age was 76.5 years \((p = 0.270)\), 34.8% were men \((p = 1.0)\), 30 (75.8%) patients were living alone \((p = 0.030)\), and 16 (40.6%) were dependent on family support \((p = 0.164)\). Using a t-test we compared the baseline scores of the patients who dropped out with those of the patients who remained in the study. All the scores were normally distributed which was ascertained using an F-test.

The dropouts had the following scores on the eight subscales of SF-36: physical function 19.5 (22.8) \((p = 0.000)\), role physical 10.2 (28.5) \((p = .0.377)\), bodily pain 24.6 (15.9) \((p = 0.002)\), social function 43.0 (29.5) \((p = 0.020)\), role emotion 27.7 (32.5) \((p = 0.092)\), general health 43.0 (19.5) \((p = 0.000)\), vitality 32.2 (23.1) \((p = 0.013)\) and mental health 60.5 (25.0) \((p = 0.382)\).

The phone support and counselling was given 15.9 (3.3) and 68.5 (10.7) days after discharge from hospital. The phone contact with the patients lasted between 10 and 30 min with a mean of 19.4 (6.4) min for the first interview and 22.1 (4.9) minutes for the second \((p = 0.001)\).

**Outcomes**

Using paired a t-test, we compared the changes over time in the intervention and control groups. Both the control and the intervention patients reported significant changes in health status (SF-36) from their preoperative status to 3 and 9 months after surgery, but the intervention patients reported significantly higher changes in health status within the areas of Physical function, general health perception and mental health at 3 months. The mean QALYs are given in Table 2. In the control group the quality-adjusted life years increased from 19.1% at baseline to 3 months after surgery and with 20.8% at baseline to 9 months after surgery. In the intervention group the increase was 26.9% at baseline to 3 months and 29.2% at baseline to 9 months after surgery.

**Discussion**

To our knowledge, no RCT studies have been conducted which describe health-related quality of life based on health status using the SF-36 in which the control group received conventional treatment and the intervention group received both conventional treatment and telephone intervention. To demonstrate the validity of this study further studies using the same procedure are needed. The resulting assessment of the improvement in patients’ self-reported health has been presented both in the form of SF-36 scores and as QALYs, but since the latter was obtained from the former they do not represent new independent findings. For this we would need patient reports using another instrument such as the EQ-5D which is now widely used in health economic assessments. In addition to offering new evidence on the effects of the intervention, such data would shed light on the usefulness of each instrument for measuring gains in health-related quality of life.

**Conclusion**

Both the control and the intervention patients reported significant changes in health status (SF-36) from their preoperative status to 3 and 9 months after THR. Both intervention and control patients seem to gain QALYs after THR. There was a significant gain in QALYs in both groups. However, no statistically significant or clinically significant differences between the two groups were observed within the follow-up time. Further studies including a larger population may look into this problem.

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