The Effect of Waiting Time on Health-Related Quality of Life, Pain, and Physical Function in Patients Awaiting Primary Total Hip Replacement: A Randomized Controlled Trial

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ABSTRACT

Objective: This prospective randomized study assessed the effect of waiting time (WT) on health outcomes in Finnish patients admitted to hospital for primary total hip replacement (THR).

Methods: A total of 395 consecutive patients with a need for a primary THR because of osteoarthritis and who were placed on the waiting list between August 2002 and November 2003. After placement on the waiting list, the patients were randomly assigned to a short WT (≤3 months) group (n = 174) or a nonfixed WT group (n = 221). The patients completed self-administered questionnaires at the time of placing on the waiting list and at hospital admission. Health-related quality of life was measured by the generic 15D instrument. Hip pain and function were measured by the patient self-report Harris hip score (HHS).

Results: Of the 395 patients, 312 (79%) completed the follow-up (140 patients with short and 172 with nonfixed WT). At admission, the mean 15D scores for patients with short and nonfixed WT were 0.784 and 0.783, respectively. In the intention-to-treatment analysis, the difference between the groups (Δ0.001, 95% confidence interval [CI]: –0.019 to 0.021) was not statistically significant or clinically important. The mean self-report HHS in patients with short WT was 43.5, and among those with nonfixed WT was 41.9. The difference (Δ1.6, 95% CI: –1.77 to 4.87) was not statistically significant.

Conclusion: Both generic and disease-specific measures revealed that longer WTs did not result in poorer health status at admission.

Keywords: access to health care, effectiveness, health-related quality of life, osteoarthritis, randomized clinical trial.

Introduction

Equal access to treatment is a key performance indicator of medical care in Finland. According to the Organization for Economic Co-operation and Development (OECD), comparative analysis of 20 OECD countries reported at the beginning of the 21st century that waiting times (WTs) are a serious health policy concern. When comparing common surgical procedures, Finland and the United Kingdom followed by Denmark, Norway, Australia, and Canada were the countries with the longest WTs [1].

Major joint replacement is an example of surgery with a high volume of demand and relatively long waiting periods for patients. Interest in examining the relationship between health status and time spent waiting for surgery has increased since the beginning of 2000. The majority of studies have found no relationship between health-related quality of life (HRQoL) and time spent on the elective waiting list [2–4]. Nevertheless, some disease-specific instruments have indicated significant deterioration in physical function and increase in pain while waiting [5,6]. A prospective Canadian study concluded that clinically important losses in HRQoL and mobility occur in total hip arthroplasty patients waiting more than 6 months [7]. Further, some studies [8,9] have shown that patients in a later phase of disease do not achieve the same level of outcome as those with better preoperative function, a justified reason for paying attention to the changes in health status while waiting.

Inconsistency in empirical results is partly explicable because of differences in study settings, measures (disease specific or generic), sample size, and follow-up period. The absence of controlled trials that randomly assign patients to specific WT prevents the establishing of a relationship between the length of wait and the health outcome [7].

The aim of this prospective, multicenter, randomized controlled trial was to assess the relationship between HRQoL, pain, physical function, and WT in total hip replacement (THR) patients with short WT and those where the WT was not fixed in advance, but the patient was following the hospital’s routine practice.

Methods

Study Population

Patients were enrolled into this study in three Finnish hospitals (Helsinki University Central Hospital [HUCH] Surgical Hospital, Helsinki; HUCH Jorvi Hospital, Espoo; and Coxa Hospital for Joint Replacement, Tampere). Two hospitals were university hospitals providing services for municipalities in the capital area. The third hospital is specialized in endoprosthetic surgery and provides services for municipalities in the capital area. The third hospital is specialized in endoprosthetic surgery and provides services for municipalities in the capital area.

The inclusion criteria were: a need for a primary unilateral or bilateral THR because of osteoarthritis (OA) as evaluated by the orthopedic surgeon, aged 16 years or older, patient was placed on
the waiting list in a research hospital, and the patient was willing and mentally able to participate in the study. Patients with rheumatoid arthritis, fractures, hemophilia, and deformity were excluded. The study had ethical approval from the HUCH Surgery Ethics Committee (registration number 134/E6/02).

Randomization
Consecutive patients were recruited into the study through regular contact with the orthopedic surgeons and nursing staff between August 2002 and November 2003. The last patient was admitted to hospital in May 2005. Patients came for an outpatient orthopedic surgeon assessment with a referral from a health center, local hospital, or a private physician.

After being placed on the waiting list according to clinical criteria, those meeting the inclusion criteria were asked to take part in the study. Those willing to participate were randomly assigned to either short (maximum 3 months) or nonfixed WT (patient received surgery according to the hospital’s routine procedure from the date he or she was added to the waiting list to the date of surgery).

The patients were recruited into the study in four (at one hospital in three recruitment periods) recruitment periods of 3 months (Table 1). The patients in the short WT group were operated within 2 weeks after each recruitment period, and they waited maximum 3 months for the surgery. This arrangement was needed because operating rooms for the surgeries of the short WT patients had to be booked in advance before recruitment. All patients placed on the waiting list because of OA of the hip joint had a chance of getting recruitment into the study (either into the short or nonfixed WT group). Hospitals’ capacity to operate patients in maximum 3 months was limited, and thus, the patients were allocated in unequal numbers to either short (n = 174) or nonfixed (n = 221) WT.

The tasks of generating the random sequence and implementing the assignment were separated between researchers and clinical staff. The random allocation sequence was drawn up using a computer-generated randomization list. In each hospital, after a patient was placed on the waiting list, was informed of the study, and had provided a signed consent, the patient’s named nurse assigned participants to their groups using consecutively numbered, sealed, opaque envelopes. A separate randomization procedure was performed within each hospital.

Table 1 Recruitment periods

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<tr>
<th>Recruitment period</th>
<th>Hospital 1</th>
<th>Hospitals 2 and 3</th>
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<td>I Recruitment</td>
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<tr>
<td>December 1, 2002</td>
<td>September 2 to November 30, 2002</td>
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<td>February 28, 2003</td>
<td>II Recruitment</td>
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<td>February 3 to May 30, 2003</td>
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<td>August 18 to October 31, 2003</td>
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<td>IV Recruitment</td>
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<td>August 18 to October 31, 2003</td>
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Primary analyses were based on the intention-to-treat (ITT) principle, and comparisons were between the randomized groups. Comparative analyses of baseline sociodemographic and clinical characteristics between patients who completed the questionnaires (baseline and admission) and those lost to follow-up were carried out using either the independent sample t test or the chi-square test depending on the level of measurement. In a further per-protocol analysis, we excluded those short WT patients who were admitted beyond short WT (WT > 3 months). In addition, linear regression analysis was used as a supplemen-
ductory analysis to determine the relationship between WT and HRQoL at admission with WT as an independent variable.

The group differences in the 15D score, pain, ADL, and gait were tested by the independent sample t test. Confidence intervals (CIs) of 95% were calculated for mean differences in the outcomes at admission. All differences are presented as short WT minus nonfixed WT. Two-sided P-values were calculated in all analyses with the minimum significant level set at 5%. Data analyses were performed using SPSS for Windows, version 12.0.1 (SPSS Inc., Chicago, IL, USA).

Missing values for the 15D dimensions were predicted by regression models with the responses on the other dimensions, age, and gender as explanatory variables [10]. A missing value was substituted if a minimum 80% of responses on the dimensions were present.

Results

Participants

Of the 503 eligible patients, 108 (21.5%) patients (70 females) with a mean age of 70 (SD 10.4) years were excluded after being informed on the study (Fig. 1). Thus, 395 patients were randomly allocated into short WT \( n = 174 \) or nonfixed WT \( n = 221 \). A total of 373 patients completed the baseline questionnaire. Some 61 patients were lost to follow-up between the baseline and admission measurements and were not included in the final analyses. Both the baseline and admission questionnaires were filled in by 312 patients, of which 140 were in the short WT and 172 in the nonfixed WT group.

Baseline Characteristics

The baseline characteristics of the patients are presented in Table 2. The patients with comorbidity totaled 210, while patients without comorbidity totaled 102. The most common coexisting disease was cardiovascular disease, followed by high cholesterol, diabetes mellitus, and endocrinological problems. Both randomized groups were comparable in baseline demographic and clinical characteristics. The mean (SD) baseline 15D score of the 312 patients was 0.783 (0.087). The majority of the patients \( n = 271 \); 88.6% experienced moderate to severe pain, and six (2.0%) patients were totally disabled. A total of 158 (51.3%) patients used walking support, and 294 (95.5%) patients had difficulties with climbing stairs.

Of the patients who completed the questionnaires, 113 (36%) waited 0–3 months and 78 (25%) waited more than 3 months but less than 6 months. A total of 121 (39%) patients waited more than 6 months, of which 26 patients waited a year or more.

A comparison between patients who completed the questionnaires (baseline and admission) and those who were lost to follow-up showed that those who were lost to follow-up were older than patients who completed the questionnaires \( t = 2.1, P = 0.034 \), were more often living alone \( \chi^2 = 11.0, P = 0.001 \), and scored lower for gait \( t = 2.5, P = 0.014 \).

Outcomes

In patients with short WT, the mean (SD) 15D score at admission was 0.784 (0.089), and in nonfixed WT patients 0.783 (0.090) (Table 3). The mean difference (Δ0.001) between the groups was not statistically significant or clinically important.

Figure 1 Flow of participants.
A per-protocol analysis was performed as a supplementary analysis. In the short WT group, those compliant with allocated WT (n = 87) and all patients in the nonfixed WT group (n = 172) were included in the analysis. Similar results were obtained in a per-protocol analysis, and WT did not show a significant effect on the 15D score at admission (A = 0.003).

A linear regression analysis was performed to estimate the relationship between WT and 15D score at admission. WT did not show a significant effect on the 15D score at admission (β = 0.0002, P = 0.867, 95% CI: -0.002 to 0.002, data not shown).

The patient self-report HHS, pain, ADL, and gait were used as secondary outcome measures. At admission, the mean HHS scores in the short and nonfixed WT groups were 43.5 (SD 15.1; range 6–90) and 41.9 (SD 14.5; range 2–80), respectively. In patients with short WT, the mean (SD) pain score was 17.8 (8.0), and in patients with nonfixed WT, 17.1 (8.6). The pain score of HHS at admission ranged from 0 (totally disabled, pain at rest, n = 13, 4.3%) to 44 (no pain, n = 5, 1.6%). A total of 22 patients (7.2%) reported mild pain after unusual activity, 157 (51.5%) reported moderate pain, and 101 (33.1%) reported marked or severe pain.

With regard to function, the great majority of patients reported limitations in ADL and gait. At admission, 128 patients (41.7%) did not need any support and the rest 178 (58.3%) patients used cane, crutch, and walker, or were totally unable to walk.

The results of the ITT analysis showed that there were no statistically significant differences in the self-report HHS total score and the levels of pain, ADL, and gait between the groups at admission (Table 3). In the per-protocol analysis, no statistical differences between the groups were found (Table 4).

### Conclusion

The main findings of our study are: 1) at admission, there were no statistically significant and clinically important differences in HRQoL, pain, and function between the groups with different
average WT; and 2) both disease-specific and generic measures supported the conclusion that WTs were unrelated to the health status at admission.

Our findings corroborate previous studies that have found no significant difference in HRQoL between patients with short and longer waits [3,4]. Those studies were, however, not based on a randomized design, and thus in those studies, patients with more severe symptoms may have had surgery more quickly than those with less severe symptoms and longer WT.

In the test group, WT was limited to 3 months reflecting the preparatory work of the national working group on access to care and waiting list management [18]. According to the working group, medically justified treatment must be provided within 3 months, or at the very latest, 6 months. In this respect, the finding that there was no difference in health status at admission between patients with short WT (median WT 3 months) and those with nonfixed WT (median 6 months) may support guidelines for medically justified treatment within 6 months or even beyond instead of 3 months. Nevertheless, although longer WTs did not result in poorer health status at admission, the patients suffered from restrictions in health such as moderate to severe pain and limitations in function at both measurement points.

One of the strengths of this multicenter study was that patients awaiting primary THR were prospectively followed from the time the patient was placed on the waiting list to the time of admission, with WTs calculated exactly. Further, participants were randomly assigned to either short or nonfixed WT, providing evidence of the effect of WT on preoperative health status. The findings were also based on the simultaneous use of both a generic and disease-specific instrument as outcome measures, allowing a more global assessment of THR than if the measures were utilized separately [19].

The sample was drawn from three large hospitals across two hospital districts, and the sex and age structure of the patients in this study were similar to those of Finnish THR patients [20]. Further, the median WT for the patients with nonfixed WT (194 days) was longer than was the median WT for Finnish patients awaiting primary prosthetic replacement of hip joint in 2003 (155 days), although the WT in this study was comparable to national WTs when taking into account the significant regional differences [20]. For example, in 2002, the shortest median WT for the primary hip replacement was 84 days, and the longest 327 days when comparing the 20 hospital districts [21]. In relation to some countries, the median WT in patients with nonfixed WT was long. For example, in Australia, the median inpatient WT of the THR patient admitted in 2000 was 98 days, in Canada (British Columbia) 112 days, and in Norway 99 days [1].

Most patients (81%) were residing in the urban area, which may limit our study’s generalizability to rural populations. A previous study has shown that urban THR patients may differ from rural patients with respect to pain threshold and perceptions on function [22].

To avoid selection bias among the patients, consecutive patients placed on the waiting list were recruited into the study. Nevertheless, a total of 108 eligible subjects were excluded from the trial. The majority of those excluded were not willing to participate in the study and they did not give consent. That those excluded (mean age of 70 years) were older than completing participants (mean age of 65 years) may have resulted in more positive outcomes if only those with relatively mild disease at the time of listing for surgery were randomized. Completing participants experienced, however, substantially poorer HRQoL compared to that of an age-matched general Finnish population sample [23] and the majority of patients experienced moderate to severe pain and limitations in function while waiting.

A selection bias may have also resulted if the research hospitals were not representative of the Finnish hospitals as a whole. The sample was, however, drawn from three large hospitals across two hospital districts, and the sex and age structure of the patients who completed the trial were representative of Finnish THR patients [21].

A limitation of the study was that 53 patients in the short WT group waited longer than 3 months before being operated on. This may have resulted in an underestimation of the WT effect. The primary analysis was, however, based on the ITT principle to address the question of clinical effectiveness and treatment policy, and to avoid the bias associated with a nonrandom loss of participants. The additional analyses—a per-protocol analysis where the short WT patients who were admitted beyond short WT were excluded from the analysis and a regression model with WT as an independent variable—supported the main finding and did not show a statistically significant or clinically important difference in HRQoL between the randomized groups. Nurse’s feedback on the study protocol revealed explanations of why 53 patients in the short WT group did not receive the allocated intervention in time. Some patients wanted to postpone surgery that inconveniently arrived too soon, some were not clinically ready for surgery, randomization had not been clearly noticed in the hospital, or there was no capacity to carry out surgery within 3 months. These explanations relate to current clinical practice in Finnish health care. The nationwide principles of access to health care within a reasonable period came into force in March 2005. Although “maximum WT guarantee” has improved access to treatment, some areas have reported problems in access to care because of the hospitals’ limited surgical capacity or patients’ unwillingness to care within the time specified [24].

For ethical reasons, double-blinding was not possible and the patients were aware of the length of wait. Thus, the knowledge that they were accessing treatment within 3 months may have influenced the patients’ self-evaluation of their HRQoL. For example, Achat et al. [25] have found that optimism in older patients is associated with higher scores in health status.

Patients’ subjective perceptions as measured by validated and standardized generic health measurement instruments are of

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<td><strong>Outcome measure</strong></td>
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<td>Self-report HHS</td>
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<td>ADL</td>
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†Number of observations varies because of missing values.

ADL, activities of daily living; CI, confidence interval; HHS, Harris hip score; WT, waiting time.
clinical relevance when planning and developing recommendations for priority setting in clinical decision-making. In this study, longer WT did not result in poorer HRQoL at admission, but patients seemed to be tolerant of moderate waiting. We even found that some patients wanted to postpone surgery. Nevertheless, OA is a slowly progressive disorder, and thus it is essential to identify the patients in the poorest health. The findings of this study have health political relevance when searching for more sustainable ways of allocating WTs, and developing recommendations and criteria for assessing health-care needs for elective treatment. Continued investigation of long-term effects and the stability of the effects of WT, as well as the effects of waiting on the demand for social and health services and medication, are becoming increasingly necessary and important.

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References