The effect of waiting time on health and quality of life outcomes and costs of medication in hip replacement patients: a randomized clinical trial

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Summary

Objective: To evaluate the effect of waiting time on health and quality of life outcomes and costs of medication in total hip replacement (THR) patients in a randomized clinical trial.

Methods: 395 THR patients were recruited into the study. When placed on the waiting list, patients were randomized into a short (<3 months) or a non-fixed waiting time (NFWT) (>3 months) group. In the final analyses 309 patients (179 women) with a mean age of 65 years were included. Health-related quality of life (HRQoL) (generic 15D), and pain and function (modified Harris Hip Score (HHS)) were calculated when placed on the waiting list, at hospital admission, and at 3 and 12 months postoperatively. The costs of disease-specific medication were calculated at the same measurement points. All analyses were performed using the intention-to-treat (ITT) principal.

Results: Of the recruited patients, 309 (78%) completed the follow-up (short group 140 and non-fixed group 169 patients). The mean waiting time was 74 days in the short and 194 days in the NFWT groups. In the ITT analyses there were no statistically significant differences between the groups in the weekly use and costs of medication, HRQoL or HHS at baseline, at admission, or 3 or 12 months after surgery. The only difference was in total medication costs during the waiting time period, at EUR 83 and 171, respectively.

Conclusions: The length of the waiting time did not generate different effects on the studied health and quality of life outcomes of the randomized groups. However, those in short waiting time group reached earlier better HRQoL.

Key words: Waiting time, Randomization, HRQoL, 15D, Harris Hip Score, Medication.

Introduction

According to the Health 2000 Health Examination Survey in Finland, 12% of the population aged over 65 had hip arthritis1, while 8460 total hip replacements (THR) were performed in 2004 in the median waiting time to surgery being 153 days. Between 1987 and 2004, the THR rate rose on average 5% annually2. In 2005, the Finnish Social Insurance Institution paid EUR 85 million in drug reimbursements to 990,637 patients with musculoskeletal diseases, with the mean cost per patient being euro (EUR) 86 per year3.

Earlier studies have established that arthritis causes pain, reduces the range of motion, and creates difficulties in participating in daily activities, which in turn affect quality of life. Because the waiting times for surgery are long, the disease becomes an increasingly chronic burden to patients4-7. Moreover, the duration of conservative treatment and the use of medication (analgesics and anti-inflammatory drugs) increase with longer waiting time. Prior studies have demonstrated that poorer health status preoperatively is predictive of higher out-of-pocket costs for patients during the first year postoperatively8, and waiting more than 6 months is associated with higher mean total costs while longer waiting times result in deterioration in physical function while waiting9.

The aim of this prospective randomized controlled trial was to identify the effects of waiting time on health and health-related quality of life (HRQoL) outcomes and the use and costs of disease-specific medication (DSM) among two patients group; a short waiting time group (SWT) (<3 months) and a non-fixed waiting time (NFWT) group (>3 months). Measurements took place when first placed on the waiting list, at admission, and 3 and 12 months after the THR.

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To our knowledge no prior studies have looked at the effect of waiting time on HRQoL and the use and costs of DSM among hip replacement patients in a randomized study design. The question of whether the length of waiting time for THR affects the use and costs of medication and health and quality of life outcomes is a contested issue.

Methods

DATA COLLECTION

Between August 2002 and November 2003, 513 THR patients in three Finnish hospitals were invited to participate in the study: two of the hospitals (the Surgical Hospital and Jorvi Hospital) are part of the Helsinki University Central Hospital, while the third is the Coxa Hospital for Joint Replacement. Patients were recruited into the study through contact with orthopedic and practice staff.

The key inclusion criteria were the need for a primary THR due to osteoarthritis of the hip joint as evaluated by the hospital surgeon, the patient was aged 16 or older and placed on the waiting list in a research hospital, and the patient was willing and mentally able to participate in the study. The key exclusion criteria were patients with rheumatoid arthritis, fractures, and congenital haemophilia or congenital deformities.

RANDOMIZATION

When placed on the hospital waiting list, patients were randomly assigned to one of two groups: (1) a SWT with a maximum wait of 3 months, or (2) a NFWT with surgery performed according to the hospital’s routine procedure, with the waiting period measured from the date the patient was added to the waiting list to the date of admission for surgery. The number of patients placed on the waiting list varied from 1 month to another, being specific to each hospital. Therefore, no advance estimate could be made of the number of patients to be placed on the list. The patients randomized into the SWT group could only be operated on in one of four operating periods during the year, and only half of the hospital’s 1-month surgical capacity could be allocated to the SWT group, so the number of SWTs was restricted and determined specifically for each hospital.

Patients were recruited into the study in over three (for one of the hospitals) or four recruitment periods (for the other two hospitals), each period lasting 3 months in order to avoid the waiting time for the SWT group exceeding 3 months. Patients in the SWT group were operated within 2 weeks following the end of each recruitment period. The size of the NFWT group was not restricted so as to ensure that all eligible patients placed on the waiting list had an opportunity to be recruited to the study. Randomization took place during the whole recruitment period (3 months), allowing everyone the possibility of a SWT. The two patient groups therefore differed in size.

Computer-generated randomization sequences were produced by the National Research and Development Centre for Welfare and Health and supplied to the hospitals using consecutively numbered and sealed opaque envelopes. The patient’s named nurse assigned participants to their groups after the decision for surgery had been made. The randomization envelopes contained information on whether the patient belonged to the SWT or NFWT group. Surgeons were blind to patient allocation. For ethical reasons double-blinding was not possible.

Patients completed a self-administered questionnaire when placed on the waiting list, at admission, and at 3 and 12 months postoperatively. The

Fig. 1. Flow of patients through the trial.
**Table 1**

Baseline characteristics of randomized groups and those lost to follow-up

<table>
<thead>
<tr>
<th>Characteristics at baseline</th>
<th>SWT (n = 145)</th>
<th>NFWT (n = 175)</th>
<th>Lost to follow-up (n = 64)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (mean ± SD)</td>
<td>66 ± 9.8</td>
<td>64 ± 10.1</td>
<td>68 ± 10.1</td>
<td>0.053</td>
</tr>
<tr>
<td>Females [n, (%)]</td>
<td>88 (49.2)</td>
<td>91 (52.3)</td>
<td>38 (62.3)</td>
<td>0.539</td>
</tr>
<tr>
<td>Housing [n, (%)]</td>
<td>50 (33.6)</td>
<td>45 (26.5)</td>
<td>20 (33.9)</td>
<td>0.313</td>
</tr>
<tr>
<td>Living alone</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic education [n, (%)]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower level</td>
<td>118 (79.2)</td>
<td>133 (78.7)</td>
<td>46 (78.0)</td>
<td>0.494</td>
</tr>
<tr>
<td>Comorbidity, yes [n, (%)]</td>
<td>103 (69.1)</td>
<td>116 (68.2)</td>
<td>40 (67.8)</td>
<td>0.504</td>
</tr>
<tr>
<td>Medication to arthritis, yes [n, (%)]</td>
<td>136 (91.3)</td>
<td>149 (87.6)</td>
<td>56 (94.9)</td>
<td>0.136</td>
</tr>
<tr>
<td>Medication costs €/week ± SD</td>
<td>5.4 ± 5.6</td>
<td>6.3 ± 7.0</td>
<td>5.5 ± 7.2</td>
<td>0.997</td>
</tr>
<tr>
<td>BMI ± SD</td>
<td>27.9 ± 3.9</td>
<td>27.7 ± 3.8</td>
<td>27.7 ± 4.6</td>
<td>0.865</td>
</tr>
<tr>
<td>HHS ± SD</td>
<td>43.9 ± 13.5</td>
<td>44.09 ± 14.4</td>
<td>44.3 ± 12.9</td>
<td>0.853</td>
</tr>
<tr>
<td>Pain score ± SD</td>
<td>16.8 ± 7.6</td>
<td>17.4 ± 6.8</td>
<td>16.2 ± 7.0</td>
<td>0.388</td>
</tr>
<tr>
<td>Function score ± SD</td>
<td>27.1 ± 8.6</td>
<td>27.2 ± 9.0</td>
<td>27.7 ± 8.1</td>
<td>0.612</td>
</tr>
<tr>
<td>15D score** (mean ± SD)</td>
<td>0.767 ± 0.09</td>
<td>0.764 ± 0.12</td>
<td>0.753 ± 0.01</td>
<td>0.295</td>
</tr>
</tbody>
</table>

*Between patients who completed all questionnaires and those lost to follow-up.

†Body mass index (kg/m²).

‡The scale 0–91, worst to best.

**The scale 0–1, worst to best.

quetenaires were either distributed to the patients at the hospital or in some cases mailed to patients, as happened with one hospital for the third and fourth questionnaires. All questionnaires were returned by post. Common guidelines for administering the questionnaires were provided in each hospital. The patients completed a sociodemographic form, reported their weights. The index score (15D score) ranges from 0 (dead) to 1 (completely healthy). Completing the 15D questionnaire takes 5–10 min and it describes the HRQoL of the respondent at present. A difference of >0.03 in the 15D score is clinically important in the sense that on average people can feel the difference. In most of the important properties (reliability, content validity, sensitivity in terms of discriminatory power and responsiveness to change) the 15D compares at least equally well with other similar instruments that produce a valuation-based single index number. By using the mean 15D scores from each measurement point and assuming a linear change in the scores between the measurement points we also estimated the possible gain in quality-adjusted life years (QALY gain) for both groups within the observation period.

The disease-specific modified HHS was used to measure hip pain and function. The self-report HHS consists of two sections: pain (0–44 points) and functional activities of daily living and gait (0–47). The total score ranges from 0 to 91, with higher scores representing better health states. A further 9 points of the total HHS would normally be assigned to describing deformity and range of motion, but were excluded because these items could not be measured in a patient self-report questionnaire. The performance of self-reported HHS is comparable to that of surgeon-assessed HHS and has shown to be less burdensome to patients than physician-administered HHS. The HHS and 15D score serve as measures of disease severity at baseline (preoperatively).

The use of DSM (analgesics and anti-inflammatory drugs) during the week preceding every measurement point was measured based on self-report. The unit costs of medication per tablet were obtained from CD-Pharmacy. The costs of medication during the waiting period were calculated as a product of the weeks spent on the waiting list and the medication costs per week. The calculations for medication costs were made at each of the four measurement points.

**Statistical analysis**

The sample size estimate was based on the primary outcome variable 15D. A subgroup of 177 patients would provide the 80% power (two-tailed α error 5%) to detect clinically important differences (Δ0.03) in the 15D score between the randomized groups.

Primary analyses were conducted with an intention-to-treat (ITT) principle, so that patients were followed in the groups to which they were randomly allocated. Also a supplementary per-protocol analysis was carried out at admission by excluding the patients from SWT group who were admitted beyond the short waiting time (waiting time >3 months). When comparing the mean scores of 15D, total HHS, pain, function and costs of DSM at the various points of follow-up between SWT and NFWT, general linear model for repeated measures was used. Univariate (tests of within-subject effects) P-values were calculated, while a P-value <0.05 was considered statistically significant. Also the mean differences, standard deviations and confidence intervals (CIs) of 95% of the variables 15D, total HHS, pain, function and costs of DMS were presented for the estimated effect.

Descriptive characteristics at baseline in the randomized groups and the patients who were lost to follow-up were compared using either the F-test or
The baseline characteristics of the groups were similar and are reported in Table I. The mean (±SD) 15D score in the SWT group was 0.767 (±0.09) and 0.764 (±0.12) in the NFWT group; the difference was not statistically significant or clinically important (P = 0.295). The mean (±SD) total HHS was 43.9 (±13.6) and 44.1 (±14.1) in the SWT and NFWT group, respectively (P = 0.853). The percentage of patients receiving DSM was 91% (n = 136) in the SWT and 89% (n = 149) in the NFWT group. The mean weekly medication costs were EUR 5.4 and EUR 6.3 in the SWT and NFWT groups, respectively. The difference was not statistically significant (Table I).

A comparison between patients who completed the questionnaire and those who were lost to follow-up showed no statistically significant differences between the groups (Table I).

Table II
Outcomes at admission, ITT-analysis

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>SWT mean (±SD) (n = 139−140)</th>
<th>NFWT mean (±SD) (n = 167−169)</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>15D score*</td>
<td>0.768 (0.107)</td>
<td>0.769 (0.107)</td>
<td>0.001</td>
<td>-0.022 to 0.024</td>
<td>0.931</td>
</tr>
<tr>
<td>Self-report HHS†</td>
<td>42.99 (15.32)</td>
<td>41.73 (14.08)</td>
<td>-1.262</td>
<td>-5.233 to 1.816</td>
<td>0.456</td>
</tr>
<tr>
<td>HHS pain score</td>
<td>17.63 (7.64)</td>
<td>17.14 (8.55)</td>
<td>-0.493</td>
<td>-2.332 to 1.346</td>
<td>0.602</td>
</tr>
<tr>
<td>HHS function score</td>
<td>25.86 (9.08)</td>
<td>24.79 (8.42)</td>
<td>-1.067</td>
<td>-3.051 to 0.915</td>
<td>0.29</td>
</tr>
<tr>
<td>Costs of medication†</td>
<td>5.56 (6.80)</td>
<td>5.63 (6.22)</td>
<td>0.793</td>
<td>-1.399 to 1.557</td>
<td>0.196</td>
</tr>
<tr>
<td>Waiting time, days</td>
<td>74 (145)</td>
<td>194 (175)</td>
<td>117.80</td>
<td>93.03 to 142.57</td>
<td>0.000***</td>
</tr>
</tbody>
</table>

***P < 0.001.
*The scale 0−1, worst to best.
†The scale 0−91, worst to best.
**Medication costs during the waiting time.

The most frequently quoted reasons for refusal were being too tired or unwillingness to complete questionnaires. Thus, 395 patients after providing a signed informed consent were randomized, seven were operated on elsewhere, operations for 12 patients were canceled, and too tired or unwillingness to complete questionnaires. Thus, 395 patients after providing a signed informed consent were randomized, seven were operated on elsewhere, operations for 12 patients were canceled, and seven died while waiting and 45 did not return the questionnaire at admission. All analyses were performed using SPSS versions 14 and 16 for Windows.

Results

Of the 513 eligible patients invited to participate in the study, 118 refused to participate and were excluded. Their mean age was 70 years (SD ± 11) and 64% were women. The most frequently quoted reasons for refusal were being too tired or unwillingness to complete questionnaires. Thus, 395 patients after providing a signed informed consent were randomly allocated to either the SWT (n = 174) or NFWT (n = 221) group. Of these patients, 86 were lost to follow-up during the waiting time and were not included in the final analyses. Of these patients 11 did not return the questionnaire at baseline, although they had signed informed consent and were randomized, seven were operated on elsewhere, operations for 12 patients were canceled, and seven died while waiting and 45 did not return the questionnaire at admission. All analyses are based on 309 (78%) patients (179 women) with a mean (SD) age of 65 (±9.9; range; from 33 to 87) years, of which 140 were in the SWT and 169 in the NFWT group (Fig. 1).

Table III
Outcomes at admission, per-protocol analysis

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>SWT mean (±SD) (n = 92)†</th>
<th>NFWT mean (±SD) (n = 170)</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>15D-score*</td>
<td>0.764 (0.11)</td>
<td>0.770 (0.11)</td>
<td>0.004</td>
<td>-0.023 to 0.032</td>
<td>0.733</td>
</tr>
<tr>
<td>Self-report HHS†</td>
<td>42.95 (16.27)</td>
<td>41.73 (14.0)</td>
<td>-1.251</td>
<td>-5.198 to 2.766</td>
<td>0.548</td>
</tr>
<tr>
<td>HHS pain score</td>
<td>17.42 (8.18)</td>
<td>17.14 (8.55)</td>
<td>-0.283</td>
<td>-2.432 to 1.866</td>
<td>0.795</td>
</tr>
<tr>
<td>HHS function score</td>
<td>25.90 (9.47)</td>
<td>24.80 (8.42)</td>
<td>-1.106</td>
<td>-3.442 to 1.230</td>
<td>0.351</td>
</tr>
<tr>
<td>Costs of medication†</td>
<td>5.22 (6.74)</td>
<td>5.63 (6.22)</td>
<td>0.41</td>
<td>-1.277 to 2.098</td>
<td>0.632</td>
</tr>
<tr>
<td>Waiting time, days</td>
<td>59.28 (21.40)</td>
<td>218.50 (140.35)</td>
<td>159.211</td>
<td>137.79 to 180.635</td>
<td>0.000***</td>
</tr>
</tbody>
</table>

***P < 0.001.
†Weekly costs of medication in EUR (EUR is 1.6 US$).
OUTCOMES AFTER THR

The use and costs of medication had decreased in both groups at 3 months and 1 year after the THR: 43% (n = 55) in the SWT and 48% (n = 71) in the NFWT group reported using medication for arthritis. In the SWT group the weekly costs at 3 months were EUR 1.58 and in the NFWT group EUR 1.96 and after 1 year EUR 0.80 and EUR 0.98, respectively. The differences were statistically significant between different measurement points (F = 63.08; P < 0.001), but not between the randomized groups (F = 1.08; P = 0.372).

At 3 months the mean 15D score was 0.852 in the SWT and 0.859 in the NFWT group, and after 1 year 0.856 and 0.873, while the mean total HHS was after 3 months 67.02 and 67.12, respectively and after 1 year 72.18 and 74.57, respectively. The differences between the groups are not statistically significant (Table IV). There were statistically significant differences between different measurement points, but not between the randomized groups (Table V).

There was an improvement from 3 months to 12 months postoperatively in the mean 15D score and total HHS, pain and function and a decrease in the cost of medication in both groups. SWT resulted in a gain of 0.028 QALYs (area between the curves in Fig. 3) during the observation period.

Conclusions

Scientific evidence on the relationship between waiting time and THR outcomes is inconsistent and the absence of randomized trials has prevented an assessment of whether longer waiting is somehow related to health and quality of life outcomes. To our knowledge, the present study is the first to assess the use and costs of DSM in THR patients randomly allocated to short and NFWT groups. The study also analyzed whether the length of the waiting time was related to HRQoL, hip pain and function as measured by the 15D and HHS, respectively.

The main finding was that the time spent on the waiting list was not related to the weekly use and costs of DSM, with no differences found between the randomized groups. The weekly costs were almost identical in both groups at each of the four measurement points. In an earlier study among these patients it was found that they used very little health and social services during the waiting time and only a minority of patients received visits to their home from nurse, chiropodist or physician with no statistically significant differences between the four measurement points.
significant difference between the randomized groups. Similarly, the mean HRQoL scores and pain and function scores were almost identical in both groups at each of the four measurement points, and reached their highest values 12 months postoperatively. However, the SWT resulted in a small QALY gain of 0.028, and reached better quality of life 3 months earlier than those in the NFWT group.

In this study, patients’ HRQoL at baseline was deteriorated and they had pain and difficulties in functioning and daily activities. However, the length of waiting time alone did not affect HRQoL or pain and function scores, which is in line with the findings of some earlier studies. However THR has been found to be effective, with this study also showing significant improvement in HRQoL and in pain and function 3 and 12 months postoperatively in both randomized groups.

To our knowledge no studies have so far been published on the effect of waiting time on the use and costs of DSM. Fielden et al. estimated the costs and outcomes of the waiting time for THR in a prospective study. They found that waiting more than 6 months was associated with higher total costs and deterioration in physical function while waiting. These cost results are not comparable to ours, as they estimated all costs during the waiting period.

The strengths of this study were that the patients awaiting THR were prospectively followed from the time of being placed on the waiting list to admission—with waiting times recorded precisely—and for a further year of follow-up postoperatively, providing evidence of the effect of WT on pre- and postoperative health status. Further, the patients were randomly assigned to either a SWT or NFWT group. The findings were based on the simultaneous use of patient-reported generic and disease-specific instruments as outcome measures. Also the results based on ITT and per-protocol analyses indicated that there were no statistically significant differences in health outcomes between the randomized groups. This was further tested with repeated measures analyses. The within-subject test indicated that there was a significant time effect, i.e., the outcomes did change over time, but the changes were identical, which is consistent with the finding that the interaction was not significant.

Some limitations pertain to this study. First, patients who refused to participate the study were older than those in the study groups. Second, medication information was obtained only from patient self-reports, while there was no distinction between self-care and prescription medication. For temporary medication we used mean dosages. Third, a total of 49 patients in the SWT group waited more than 3 months. The reasons were hospitals’ limited capacity to carry out THR within the 3 months waiting time period or the patient’s unwillingness to have THR within 3 months. Due to these factors, the differences between the randomized groups may have been underestimated. However the primary analysis was based on the ITT principle to address the question of clinical effectiveness and to avoid the bias associated with a non-random loss of participants. In addition the supplementary per-protocol analysis at admission where the SWT patients who were admitted beyond SWT were excluded from the analysis — supported the main findings and did not show a statistically or clinically important difference in HRQoL between randomized groups.

According to this study the length of waiting time, at least as realized in practice in this study, did not result in different health outcomes in the randomized groups in three cross-sectional follow-up measurements from baseline to 1-year postoperatively. The length of the waiting time reflected in the total medication costs of the waiting period and in a small QALY gain in the SWT, as it reached the same HRQoL level as the NFWT group on average 3 months earlier.

Conflict of interest
The authors declare that they have no competing interests.

Acknowledgments
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