Operative approach influences functional outcome after DAIR for infected total hip arthroplasty

Aims
To compare the functional outcome, health-related quality of life (HRQoL), and satisfaction of patients who underwent primary total hip arthroplasty (THA) and a single debridement, antibiotics and implant retention (DAIR) procedure for deep infection, using either the transgluteal or the posterior surgical approach for both procedures.

Methods
The study was registered at clinicaltrials.gov (ID: NCT03161990) on 15 May 2017. Patients treated with a single DAIR procedure for deep infection through the same operative approach as their primary THA (either the transgluteal or the posterior approach) were identified in the Norwegian Arthroplasty Register and given a questionnaire. Median follow-up after DAIR by questionnaire was 5.5 years in the transgluteal group (n = 87) and 2.5 years in the posterior approach group (n = 102).

Results
Patients in the posterior approach group were less likely to limp after the DAIR procedure (17% vs 36% limped all the time; p = 0.005), had a higher mean Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) function score (80 vs 71; p = 0.013), and were more likely to achieve a patient acceptable symptom state for the WOMAC function score (76% vs 55%; p = 0.002). In a multivariable analysis, the point estimate for the increase in WOMAC function score using the posterior approach was 10.2 (95% CI 3.1 to 17.2; p = 0.005), which is above the minimal clinically important improvement. The patients in the posterior approach group also reported better mean HRQoL scores and were more likely to be satisfied with their hip arthroplasty (77% vs 55%; p = 0.001).

Conclusion
In patients treated with a single, successful DAIR procedure for deep infection of a primary THA, the use of the posterior approach in both primary surgery and DAIR was associated with less limping, better functional outcome, better HRQoL, and higher patient satisfaction compared with cases where both were performed using the transgluteal approach. The observed differences in functional outcome and patient satisfaction were clinically relevant.

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Introduction
Periprosthetic joint infection (PJI) is a serious complication after a primary total hip arthroplasty (THA). In acute PJI with a stable implant, infection can be eradicated in approximately 75% of the cases with debridement, antibiotics, and implant retention (DAIR). For the patient, however, functional outcome may be just as important as infection control. Infected cases successfully treated with a single DAIR procedure can have a functional outcome comparable with an uncomplicated primary arthroplasty. However, while some evidence suggests that the functional result after primary THA, and after revision THA for aseptic loosening, is worse with the transgluteal approach, it is not known whether the surgical approach used for primary and revision surgery plays a role in the functional outcome after DAIR. The two most commonly used operative approaches...
for elective THA in our country during the last three decades are the direct lateral transgluteal (Hardinge) approach and the posterior approach.\(^6\)

The aim of this observational cohort study based on data from the Norwegian Arthroplasty Register (NAR) and patient-reported outcomes was to compare the functional outcome, health-related quality of life (HRQoL), and satisfaction of patients treated for deep infection with a single DAIR procedure through the same operative approach (either transgluteal or posterior) as their primary THA.

**Methods**

**Patients and data collection.** All primary and revision THAs in Norway should be reported to the NAR. The unique identification number of each Norwegian citizen is used to link the primary THA to any subsequent revisions. The completeness of the NAR...
has been shown to be 97% for primary THAs and 93% for revisions. The surgeon registers the operation immediately post-surgery on a one-page questionnaire, which includes information on the patient’s age, sex, American Society of Anesthesiologists (ASA) class, laterality, previous surgery of the hip, date of the operation, indication for surgery, type of surgical procedure, and surgical approach. The diagnosis of deep infection is made by the surgeon immediately after revision surgery based on preoperative assessment and intraoperative findings.

Patients eligible for the study were identified in the NAR using the following criteria: a primary THA revised once due to deep infection with a DAIR procedure, with the primary THA and DAIR procedure performed through the same surgical approach, either the transgluteal or the posterior approach (Figure 1). All identified patients were sent questionnaires with a reply-paid envelope. They were asked to consent for the study and to confirm that they had indeed only undergone one revision procedure for PJI. They were asked if the infection was considered to be eradicated and to fill out the following scores: the Hip Disability Osteoarthritis Score (HOOS), the three-level Euro-Qol five-dimension index (EQ-5D-3L), and the EQ-5D visual analogue scale (EQ-VAS). The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was calculated from the HOOS. In addition, the questionnaire included questions about limping, other complications (nerve injury, dislocation, revision for other causes than infection), and overall satisfaction with the arthroplasty (see Supplementary Material). Patient satisfaction was measured on a five-point Likert scale with the choices ‘very satisfied’, ‘satisfied’, ‘somewhat satisfied’, ‘not satisfied’, and ‘not at all satisfied’. The questionnaires were sent to patients in May 2018 and non-responders received a reminder in November 2018.

Patients were excluded if they did not consent to participate, if they reported that the deep infection was not eradicated or that it occurred after revision arthroplasty, or if they had had more than one revision. Two patients in the transgluteal group reported a repair of the gluteus medius tendon as a re-revision; they were not excluded. A flowchart showing patient inclusion is shown in Figure 2.

Since a difference in re-revision rates after DAIR would influence the interpretation of the functional outcome, the two-year re-revision rates for all causes were calculated for the two approaches (both primary THA and DAIR through either transgluteal or posterior approach). These data were extracted from the NAR for the study period (Figure 1). Patients who were eligible for the study had, per the selection criteria, not been re-revised during the study period and were followed in the NAR for re-revision for two years.
Surgical approach Functional outcome Function before THA
Year THA Age at THA
ASA class at THA

Directed acyclic graph showing the causal model used as a basis for analyzing the association between surgical approach and functional outcome. Adjusting for ‘Length of follow-up’ controls for both observed and some unobserved (‘Function before THA’) confounding, as well as for selection bias (‘Response to questionnaire’). ‘Response to questionnaire’ represents an adjusted variable as only responders were included in the study. ‘Function before THA’ is an unobserved variable.

Statistical analysis. As the WOMAC score is well documented in deep infection of hip arthroplasties, the WOMAC function subscale was chosen as the main outcome measure. Tubach et al. found the minimal clinically important improvement (MCII) in the function subscale of the WOMAC score to be 8 points, while the SD of the function subscale in their sample was 16.5. To detect a difference in the function subscale of the WOMAC score of at least 8 points between the study groups with a power of 90% and \( p < 0.05 \), a total sample size of 185 patients was required.

Data were analyzed with SPSS v25.0.0.1 (IBM, Armonk, New York, USA). A \( p \)-value < 0.05 was considered statistically significant.

The HOOS and the WOMAC subscale scores are presented as normalized scores (0 to 100), with a score of 100 indicating no symptoms. Missing items in the HOOS subscales and in the WOMAC function score were handled according to the respective scoring instructions.

For the calculation of the EQ-5D-3L index score, the preference scores generated from a large European population were used. Only cases that answered all items were analyzed. The EQ-VAS scale ranges from 0 (worst possible) to 100 (best possible overall health).

Based on previous studies, the Patient Acceptable Symptom State (PASS) was defined as \( \geq 69 \) for the WOMAC function score, \( \geq 0.92 \) for the EQ-5D-3L index, \( \geq 85 \) for the EQ-VAS, and \( \geq 83 \) for the HOOS quality of life (HOOS-QoL) score.

Patient satisfaction was dichotomized to ‘satisfied’ for the categories ‘very satisfied’ and ‘satisfied’, and to ‘not satisfied’ for the categories ‘somewhat satisfied’, ‘not satisfied’, and ‘not at all satisfied’. The ASA score was dichotomized to \( \leq 2 \) and \( \geq 3 \).

The chi-squared test was used for unadjusted comparisons of proportions, the independent-samples \( t \)-test for unadjusted comparisons of means, and the Mann-Whitney U test for unadjusted comparisons of the distribution of continuous
variables. Confidence intervals (CIs) for the difference in proportions were derived using the normal approximation. The CIs for the difference in medians are presented as the Hodges-Lehmann median difference.

The variables to be adjusted for in the multivariable regression model (log-binomial regression, modelling the risk ratio (RR), and multiple linear regression) were chosen from the measured covariates, to fully explain exposure (surgical approach in this case) and the outcome, an unmeasured confounder would need to have with both the minimum strength of association on the risk ratio scale that is required to cause a difference in the prevalence of the outcome of at least the E-value (E-value = RR + sqrt{RR \times (RR – 1)}).

As an impact measure, the number needed to harm (=1/absolute risk difference) was calculated for the outcome WOMAC function score < PASS.

Sensitivity analyses. All continuous outcome measures showed ceiling effects and the data were thus left-skewed. Therefore, as a sensitivity analysis, bootstrapping was performed for the unadjusted comparison of the WOMAC function score, the EQ-5D-3L-index, and the EQ-VAS with 1,000 samples, bias corrected, and accelerated intervals.

For the reported RR for the outcome WOMAC function score < PASS, a sensitivity analysis was performed by calculating the E-value (E-value = RR + sqrt{RR \times (RR – 1)}). To quote VanderWeele and Ding, “the E-value is the minimum strength of association on the risk ratio scale that an unmeasured confounder would need to have with both the exposure (surgical approach in this case) and the outcome, above and beyond the measured covariates, to fully explain away a specific exposure-outcome association.”

Results

Patient characteristics. The patients in the study groups were similar with respect to age, sex distribution, the distribution of ASA classes, and the time that had elapsed between the primary arthroplasty and the DAIR procedure (Table I). The median length of follow-up by questionnaire was approximately twice as long in the transgluteal approach group (Table I). A total of 22 patients had a follow-up by questionnaire shorter than one year after DAIR: 18 in the posterior approach group; and four in the transgluteal approach group.

Functional outcome. The mean WOMAC function score was significantly higher in the posterior approach group (Table II).

In a multiple linear regression analysis adjusted for age, sex, ASA class, and length of follow-up by questionnaire, the posterior approach was associated with an increased WOMAC function score (β = 10.2, 95% CI 3.1 to 17.2, p = 0.005; 4.8% missing). A significantly higher proportion of the patients in the posterior approach group reported a WOMAC function score corresponding to a PASS for this score (Table II). The number needed to harm (WOMAC function score < PASS) using the transgluteal approach was 4.8 (95% CI 2.9 to 12.5). In a log-binomial regression analysis adjusted for the length of follow-up, the use of the transgluteal approach almost doubled the relative risk of having a WOMAC function score lower than the PASS (RR = 1.8, 95% CI 1.2 to 3.0, p = 0.020; 16.6% missing).

Limping, nerve injury, and prosthesis dislocations. Whereas limping was equally common in both groups before the primary THA and before revision, patients in the posterior approach group were less likely to limp after the DAIR procedure (Table III). Self-reported nerve injury was less frequent in the posterior approach group (Table III). Self-reported dislocations of the prosthesis did not differ statistically significantly between the groups (Table III).
Table III. Self-reported limping, nerve injury, and dislocations by surgical approach.

<table>
<thead>
<tr>
<th>Limping/adverse event</th>
<th>Transgluteal approach (n = 87)</th>
<th>Posterior approach (n = 102)</th>
<th>Difference between groups, % (95% CI)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Limping before THA, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.775</td>
</tr>
<tr>
<td>Always</td>
<td>35 (40)</td>
<td>46 (45)</td>
<td>5 (-9 to 19)</td>
<td></td>
</tr>
<tr>
<td>Sometimes</td>
<td>20 (23)</td>
<td>25 (25)</td>
<td>2 (-11 to 14)</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>26 (30)</td>
<td>27 (27)</td>
<td>-3 (-16 to 10)</td>
<td></td>
</tr>
<tr>
<td>“Do not remember”</td>
<td>1 (1)</td>
<td>3 (3)</td>
<td>2 (-2 to 6)</td>
<td></td>
</tr>
<tr>
<td>Not reported</td>
<td>5 (6)</td>
<td>1 (1)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Limping before DAIR, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.895</td>
</tr>
<tr>
<td>Always</td>
<td>27 (31)</td>
<td>30 (29)</td>
<td>-2 (-15 to 11)</td>
<td></td>
</tr>
<tr>
<td>Sometimes</td>
<td>16 (18)</td>
<td>16 (16)</td>
<td>-2 (-13 to 9)</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>31 (36)</td>
<td>41 (40)</td>
<td>4 (-10 to 18)</td>
<td></td>
</tr>
<tr>
<td>“Do not remember”</td>
<td>9 (10)</td>
<td>9 (9)</td>
<td>-1 (-9 to 7)</td>
<td></td>
</tr>
<tr>
<td>Not reported</td>
<td>4 (5)</td>
<td>6 (6)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Limping after DAIR, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.005</td>
</tr>
<tr>
<td>Always</td>
<td>31 (36)</td>
<td>17 (17)</td>
<td>-19 (-31 to -7)</td>
<td></td>
</tr>
<tr>
<td>Sometimes</td>
<td>18 (21)</td>
<td>22 (22)</td>
<td>1 (-11 to 13)</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>35 (40)</td>
<td>62 (61)</td>
<td>21 (7 to 25)</td>
<td></td>
</tr>
<tr>
<td>Not reported</td>
<td>3 (3)</td>
<td>1 (1)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Nerve injury, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.054</td>
</tr>
<tr>
<td>Yes</td>
<td>15 (17)</td>
<td>13 (13)</td>
<td>-4 (-14 to 6)</td>
<td></td>
</tr>
<tr>
<td>“Do not know”</td>
<td>25 (29)</td>
<td>17 (17)</td>
<td>-12 (-24 to 0)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>46 (54)</td>
<td>71 (70)</td>
<td>16 (2 to 30)</td>
<td></td>
</tr>
<tr>
<td>Not reported</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Dislocation, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.382</td>
</tr>
<tr>
<td>Transgluteal Approach</td>
<td>7 (8)</td>
<td>5 (5)</td>
<td>-3 (-10 to 4)</td>
<td></td>
</tr>
<tr>
<td>Posterior Approach</td>
<td>3 (3)</td>
<td>1 (1)</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

*Chi-squared test.
CI, confidence interval; DAIR, debridement, antibiotics, and implant retention; N/A, not applicable; THA, total hip arthroplasty.

Table IV. Health-related quality of life measures by surgical approach.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Transgluteal approach (n = 87)</th>
<th>Posterior approach (n = 102)</th>
<th>Difference between groups (95% CI)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean EQ-5D index score (SD)</td>
<td>0.71 (0.25)</td>
<td>0.79 (0.20)</td>
<td>0.08 (0.01 to 0.15)</td>
<td>0.023*</td>
</tr>
<tr>
<td>EQ-5D index score ≥ PASS, n (%)</td>
<td>24 (30)</td>
<td>36 (38)</td>
<td>8% (-7 to 22)</td>
<td>0.296†</td>
</tr>
<tr>
<td>Not reported, n (%)</td>
<td>7 (8)</td>
<td>6 (6)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Mean EQ-VAS (SD)</td>
<td>62 (32)</td>
<td>70 (24)</td>
<td>8.3 (0.3 to 17)</td>
<td>0.043*</td>
</tr>
<tr>
<td>EQ-VAS ≥ PASS, n (%)</td>
<td>27 (31)</td>
<td>36 (35)</td>
<td>4% (-9 to 18)</td>
<td>0.530†</td>
</tr>
<tr>
<td>Not reported, n (%)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Mean HOOS-QoL (SD)</td>
<td>64 (31)</td>
<td>74 (26)</td>
<td>10 (2 to 18)</td>
<td>0.016*</td>
</tr>
<tr>
<td>HOOS-QoL ≥ PASS, n (%)</td>
<td>29 (33)</td>
<td>49 (49)</td>
<td>16% (2 to 30)</td>
<td>0.030†</td>
</tr>
<tr>
<td>Not reported, n (%)</td>
<td>N/A</td>
<td>2 (2)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Independent-samples t-test.
†Chi-squared test.
CI, confidence interval; EQ-SD-index, three-level EuroQol five-dimension index; HOOS-QoL, Hip disability and Osteoarthritis Outcome Score quality of life subscale; N/A, not applicable; PASS, Patient Acceptable Symptom State; VAS, visual analogue scale.

Health-related quality of life. The mean EQ-5D-3L-index, EQ-VAS, and HOOS-QoL scores were significantly higher in the posterior approach group (Table IV). A significantly higher proportion of the patients in the posterior approach group reported a HOOS-QoL value corresponding to a PASS for this score whereas the proportions of patients who achieved a PASS for the EQ-5D-3L-index score and the EQ-VAS did not differ statistically significantly between the groups (Table IV).

Patient satisfaction. A significantly higher proportion of patients in the posterior approach group were satisfied with their hip arthroplasty (77% vs 55%; between-group difference 22%, 95% CI 9% to 36%; p = 0.001, chi-squared test; 2.1% not reported).

In a log-binomial regression analysis adjusted for the length of follow-up by questionnaire, the use of the transgluteal approach approximately doubled the risk of not being satisfied with the hip arthroplasty (RR = 2.1, 95% CI 1.4 to 3.4; p = 0.002; 2.1% missing).

Sensitivity analyses. The unadjusted comparisons of the continuous outcome measures with and without bootstrapping gave similar results and so the comparisons without bootstrapping are presented here. The E-values for the causal association between the transgluteal approach and a WOMAC function score lower than the PASS were 3.0 for the point estimate of the RR and 1.7 for the lower limit of its CI.

Two-year re-revision rate in the NAR by approach. During the study period, 382 patients were operated with a primary THA and a DAIR procedure through the transgluteal approach, and 270 patients through the posterior approach (Figure 1). The two-year re-revision rate after DAIR for all causes was
comparable for the two groups with 26% for the transgluteal and 25% for the posterior approach (p = 0.640, chi-squared test).

Discussion
In our cohort, patients who had their primary surgery and subsequent DAIR using the posterior approach were less likely to limp after the DAIR procedure; they reported a higher mean WOMAC function score, were more likely to achieve a PASS for the WOMAC function score, and were more likely to be satisfied with their hip arthroplasty compared with patients who underwent their procedures using the transgluteal approach. In multivariable analysis, the point estimate of 10.2 for the increase in WOMAC function score using the posterior approach was larger than the MCII, which has been reported to be 8.1. The patients in the posterior approach group also reported better mean HRQoL scores.

The two-year re-revision rates reported to the NAR were comparable whether the primary THA and the DAIR procedure were performed through the transgluteal or the posterior approach. Persistent limping is a known complication after THA through the transgluteal approach and has been shown to be associated with worse patient-reported functional outcome and HRQoL. We hypothesize that the infection itself and the repeated detachment and re-suturing of the abductors increase the risk of abductor insufficiency and thus a poorer outcome after DAIR for infected THA through the transgluteal approach. Once abductor avulsion after the transgluteal approach has occurred, it is difficult to treat.

By design, with the goal of having comparable groups, patients who were registered in the NAR with more than one revision were not included in this study. Therefore, patients who were operated with the transgluteal approach and subsequently re-revised through the same approach, which likely would further damage the abductors leading to poorer outcomes, were not included. Thus, our study design may have biased our results towards smaller differences in functional outcome, HRQoL, and patient satisfaction between the two surgical approaches.

The functional outcome, HRQoL, and patient satisfaction in the posterior approach group in our study are comparable with reported results in studies of primary THAs. In a cohort of 351 patients with a mean age of 65, Escobar et al reported a mean WOMAC function score of 75.9% and a proportion of 84% for patient satisfaction one year after primary THA. The authors did not, however, specify which surgical approach to the hip joint had been used. In a cohort of 24,358 patients with a mean age of 69 years, Lindgren et al reported an EQ-5D-3L index score of 0.79 and an EQ-VAS of 76 one year after primary THA through the posterior approach. In comparison, in our posterior approach group the mean WOMAC function score was slightly higher, the EQ-5D-3L index score was the same, and the EQ-VAS and the proportion of satisfied patients were slightly lower. This would seem to indicate that the treatment of an infected THA with a single, successful DAIR, having used the posterior approach for both procedures, can result in a functional outcome, HRQoL, and patient satisfaction comparable with a primary THA not complicated by infection.

The most important strength of this study is the size of the cohort; 189 patients is a large sample of cases that received the same type of surgical treatment for an infected THA. Further, the data in the NAR were recorded prospectively. Since this is a nationwide study with wide inclusion criteria and limited exclusion criteria, our findings represent the average surgeon and patient, and should have good external validity.

On the other hand, the response rate to the patient questionnaire was rather low (62%, 226/364). Also, since this is a cross-sectional study, data on functional status and HRQoL before the primary THA were not available. This meant that we were unable to compare the degree of change in these outcome measures. However, the analysis of the PASS somewhat compensates for this shortcoming. In addition, we have no reason to believe that the preoperative functional status or HRQoL had an influence on the choice of operative approach, which more likely depended on surgeons preference.

This study is observational, and as such is prone to the risk of unmeasured confounding. However, since a deep infection after THA only occurs in about 2% of patients, a randomized controlled study with the same research question would be very difficult to conduct. Also, the E-values indicate reasonably robust evidence for a causal association between the surgical approach and the functional outcome in the present study. This is especially true in light of the fact that, according to our DAG, by controlling for the length of follow-up by questionnaire, the multivariable analysis was adjusted for the unobserved variable ‘preoperative function’ as well as for possible selection bias. However, if ‘functional outcome’ had a causal effect on responding to the questionnaire, some selection bias may still be present.

The median length of follow-up by questionnaire was significantly shorter in the posterior approach group. While the majority of patients had at least one year of follow-up, a time-point at which patient-reported outcomes generally level off, more patients in the posterior approach group had a follow-up time shorter than one year. This may have biased our results towards smaller differences in outcomes between the two groups since the patients with short follow-up had a potential for further improvement.

Follow-up by questionnaire was up to 18 years following the DAIR procedure, so with respect to limping before the primary THA and before the DAIR procedure and, to a lesser extent, adverse events such as prosthesis dislocations, some degree of recall bias can be expected.

The follow-up in the NAR for re-revision after DAIR was censored after two years. However, a two-year follow-up is generally considered adequate for orthopaedic implant infections and a longer follow-up would increase the influence of other factors on the re-revision rate, such as the choice of implant and implant fixation.

In patients treated with a single, successful DAIR procedure for deep infection of a primary THA, the use of the posterior approach in both surgeries was associated with less limping, better functional outcome, better quality of life, and higher patient satisfaction compared with the transgluteal approach. The observed differences in functional outcome and patient satisfaction were clinically relevant.
Take home message
- After a single, successful debridement, antibiotics, and implant retention (DAIR) procedure for deep infection of a primary total hip arthroplasty (THA), patient-reported outcome was better when the posterior rather than the transgluteal approach had been used for both procedures.
- The use of the transgluteal approach approximately doubled the risk of not achieving a patient acceptable symptom state for the Western Ontario and McMaster Universities Osteoarthritis Index function score and of not being satisfied with the THA.
- The treatment of an infected primary THA with a single, successful DAIR using the posterior approach for both procedures can result in functional outcome, health-related quality of life, and patient satisfaction comparable to a primary THA not complicated by infection.

Supplementary material
English translation of the non-standard questions in the questionnaire.

References

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H. Dale: Planned the study. Interpreted the data. Reviewed the manuscript.
T. M. Straume-Naesheim: Interpreted the data. Reviewed the manuscript.
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G. Hallan: Planned the study, Interpreted the data, Reviewed the manuscript.

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