Prostate Cancer

Does Preoperative Magnetic Resonance Imaging Reduce the Rate of Positive Surgical Margins at Radical Prostatectomy in a Randomised Clinical Trial?

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Abstract

Background: Magnetic resonance imaging (MRI) has the potential to help the surgeon tailor radical prostatectomy (RP) more accurately according to the location and extent of the tumour and thereby reduce the rate of positive surgical margins (PSMs).

Objective: To evaluate the benefit of performing MRI prior to RP.

Design, setting, and participants: This single-institution randomised trial included 438 patients between December 2009 and June 2012 who were scheduled for robot-assisted laparoscopic prostatectomy. The study was registered (ClinicalTrials.gov identifier NCT01347320).

Intervention: Patients were preoperatively randomly assigned to non-MRI or MRI groups.

Outcome measurements and statistical analysis: The primary end point was the difference in the PSM rates between the two groups. Secondary end points were the rates of PSMs in clinical subgroups. Summary statistics were extracted from descriptive analyses, chi-square, or Fisher exact test, and logistic regression was used to analyse the data according to the intention-to-treat principle.

Results and limitations: A total of 216 patients were randomised to non-MRI; 222 were randomised to MRI. There were 49 cases (23%) of PSMs in the non-MRI group and 43 cases (19%) in the MRI group ($p = 0.4$). The relative and absolute risk reduction was 15% and 4%, respectively. Patients with cT1 constituted 55% of the cohort, in which the rate of PSMs was 27% in the non-MRI group and 16% in the MRI group ($p = 0.035$). The relative and absolute risk reduction was 41% and 11%, respectively. A limitation was suboptimal communication between the radiologist and urologist.

Conclusions: MRI prior to RP did not reduce the overall risk for PSMs in this patient cohort. However, at subgroup analysis we observed a possible benefit of MRI in patients with cT1.

Patient summary: This study could not demonstrate a definite benefit of performing magnetic resonance imaging before surgery for all patients. However, there was a possible improved result in patients in which physical examination could not detect the cancer.

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1. Introduction

The role of magnetic resonance imaging (MRI) before radical prostatectomy (RP) is still under discussion, and routine MRI is not considered mandatory [1]. No randomised controlled trials (RCTs) have been conducted to evaluate the role of MRI prior to RP.

Ideally, MRI should detect all significant cancer foci and give an accurate T classification for optimal surgical planning. Studies have demonstrated a 80–94% detection rate for the clinically dominant tumour, the so-called index tumour [2–4]. The index tumour is associated with extraprostatic extension (EPE) when relevant, the highest Gleason score (GS), or the largest volume, in that order of priority [5–7]. When present, the secondary and tertiary tumour is the two next highest ranking tumours according to the same criteria. The sensitivity of MRI for predicting T3 is limited, ranging from 13% to 95%, depending on patient selection and the method used [8,9]. The laterality of T3 is rarely reported, although it is highly relevant when planning treatment [5,10].

Preoperative detection of T3 disease is clinically important because T3 increases the risk of positive surgical margins (PSMs), that is, cancer present on the surface of the surgically removed prostate gland. PSMs are an indicator of nonradical surgery and therefore an important parameter when assessing the surgical quality of RP [11].

The aim of this RCT was to assess the ability of MRI before RP to reduce the rate of PSMs.

2. Patients and methods

2.1. Setting

This single-institution RCT was approved by the local regional committee for medical and health ethics (S-09143c2009/2183) and registered at ClinicalTrial.gov (NCT01347320). All patients signed a letter of consent.

2.2. Study design

All patients scheduled for robot-assisted laparoscopic prostatectomy (RALP) at Oslo University Hospital, Aker, from December 1, 2009, to June 31, 2012, were candidates for the trial. Table 1 displays the baseline data of the patient cohort. During the study period, 675 patients were scheduled for RALP; 485 met the inclusion criteria, and 438 (90%) were included for intention-to-treat analyses (Fig. 1).

2.3. Exclusion criteria

Exclusion criteria were previous relevant MRI of the prostate, contraindications to MRI, and hip prosthesis.

2.4. Randomisation

Allocation (1:1) of patients to either non-MRI or MRI was based on a permuted block randomisation procedure with undisclosed and variable blocking factor. After consent was received, each patient was designated a unique, unchangeable sequentially numbered randomisation number, matching an opaque and sealed envelope, containing the corresponding intervention code (eg, non-MRI or MRI). It was not possible to replace one envelope with another, and the envelope was disposed of after each allocation. A logbook registered every procedure and was controlled several times by the responsible statistician. The envelopes were prepared by the centre of Biostatistics and Epidemiology, Research Support Service, at Oslo University Hospital and kept accessible only to E.R., who also performed the randomisation. Patients were scheduled for MRI within 2 wk.

2.5. Sample size estimation

The rate of PSMs is highly associated with the incidence of pT3, and when planning the study, the incidence of pT3 was approximately 45%. For that reason, we expected the rate of PSMs in the non-MRI group to lie between 35% and 40%. A 20% difference in the rate of PSMs between the non-MRI and MRI groups was considered clinically relevant. With a significance level of 0.05, 91–151 in each group was required to provide 80% power with a two-tailed test for two independent proportions, assuming no dropout.

2.6. Magnetic resonance imaging

The MRI radiologist had 2 yr of experience with prostate imaging at the start of the study. The radiologist was not systematically blinded to prostate-specific antigen (PSA), cT stage, and GS. All patients in the MRI group underwent 1.5-T MRI (Siemens, Erlangen, Germany) and six-channel body matrix (Siemens). The time between biopsy and MRI was 1 ± 7 wk (mean plus or minus standard deviation; range: 0–71) and between MRI and surgery was 1 ± 4 wk (range: 0–25). No patients were excluded due to haemorrhagic artefacts or poor quality of the MRI.

The sequences included 0.9-mm isotropic three-dimensional T2 and axial diffusion-weighted images (DWIs) using b50, b1000, and b2000. An apparent diffusion coefficient map was prepared from b50 and b1000. The MRI acquisition and postprocessing were previously reported in detail [12]. We used criteria for tumour detection and staging as previously specified [25,13–16]. Both T2 and DWI were used for detection and staging.

All patients also underwent axial and coronal T1-weighted imaging of the pelvis and the lumbosacral spine to evaluate possible lymph node
and skeletal metastases. These findings are not discussed in this paper. The MRI examination was completed within 20 min.

2.7. Communication with urologists prior to surgery

A schematic tumour map displaying the location and extent of the tumours (indicated in red), including possible EPE and seminal vesicle invasion, was drawn manually for every patient (Fig. 2) and shown to the surgeon before surgery in each case. In addition, the MRI information was registered in the electronic patient record system. Postoperatively, the surgeon completed a form, in which he reported whether, and in what way, MRI had changed the surgical approach.

2.8. Surgery

RALP was limited to four experienced urologists at the department. The urologists had performed an average of 103 RALP procedures (range: 78–165), and a total of 415 laparoscopic prostatectomies (range: 296–585) at the start of the study.

Figure 2 illustrates the possible approaches for the surgical dissection. The operations were classified as bilateral nerve-sparing surgery (BNS), unilateral nerve-sparing surgery (UNS), or non–nerve-sparing surgery (NNS). Nerve-sparing surgery included both intra- and interfascial dissection, as described by Walz et al [10]. The NNS could be performed as a standard bilateral extrafascial dissection or as an extended excision. The operator registered (1) the surgical plan before knowing the MRI results, (2) the surgical plan after knowing the MRI, and (3) the means by which the surgery actually was performed. We did not register whether MRI resulted in more extensive surgery anteriorly or at the bladder neck.

The planned surgical approach was based on the preoperative parameters available that included transurethral ultrasound (TRUS), digital rectal examination (DRE), GS, tumour extent in biopsies, and patient’s wish. When available, MRI was also taken into consideration.

2.9. Pathologic preparation and examination

Whole-mounted histologic sections were used as the reference standard. Specimen handling was previously described in detail [2]. The surgical margins were classified as positive when cancer tissue was present on the inked surface of the prostate specimen. The sector associated with each PSM was registered on a tumour map (Fig. 3). If a specific tumour affected the same sector as the site of the PSM, it was classified as responsible for the PSM. Each tumour and sector associated with PSMs was classified as detected by MRI or not.

2.10. Clinical, radiologic, and pathologic T classification

The staging results of the clinical examination and MRI were previously reported in detail [5] and are only briefly reported in Table 2.
Preoperative DRE and TRUS, performed by urologists, classified all patients as having clinically localised (cT1c or cT2a–c) or nonlocalised disease (cT3a–b). Due to a low number of cT3a–b cases, these patients were combined with cT2a–c in the statistical analyses. Correspondingly, MRI (rT) and histopathology (pT) classified all patients as localised (T2) or nonlocalised (T3).

2.11. Statistical analyses

The rate of PSMs in the non-MRI and MRI groups was the primary end point. Clinical subgroups were defined according to the T classification, D'Amico risk groups, GS, and surgical procedures.

The Pearson chi-square or Fisher exact test assessed differences in the rate of PSMs between the non-MRI and MRI groups and in clinical subgroups. The proportions of PSMs and odds ratios (ORs) with 95% confidence intervals (CIs) were used to describe the differences. Both absolute and relative differences (risk ratio) are reported.

Differences in the ORs of the clinical subgroups were examined by the interaction term between the non-MRI and MRI group variable and the clinical subgroup variable using logistic regression. All analyses were performed according to the intention-to-treat principle. Two-sided p values were given and not corrected for multiple testing.

IBM SPSS Statistics v.22 (IBM Corp., Armonk NY, USA) and MedCalc statistical software v.14.8.1 (MedCalc Software, Ostend, Belgium) were used for statistical analyses.

3. Results

A total of 438 patients were included in this study, in which 216 were randomised to the non-MRI group and 222 were randomised to the MRI group (Fig. 1). Table 1 shows that the groups were well balanced.

3.1. Magnetic resonance imaging tumour detection results

MRI tumour detection rates and staging results of this cohort were reported in two previous papers and are only mentioned briefly [2,5]. MRI detected 92% of the index tumour; it did not detect the index tumour in 16 patients. However, in 5 of these 16, MRI detected the second largest tumour with identical GS as the index tumour. In 11 patients with specimen GS 6 and 7, no tumour was found on MRI.

3.2. Surgical procedures

The surgeons reported that MRI altered the surgical procedure on one or both sides in 59 patients (27%), of which 30 (51%) were cT1, 29 (49%) were cT2, and 49 (83%) were rT3. All changes were in the direction of a more radical excision. There was no difference in mean age, PSA, and GS in biopsy of
patients with adjusted surgery compared with those with nonadjusted surgery. BNS was performed in 35 of 90 patients (39%) classified as rT2 versus 15 of 110 (14%) for rT3 ($p < 0.001$).

The overall rate of BNS, UNS, and NNS was 30%, 34%, and 35%, respectively. The absolute rate of BNS was 6.7% (95% CI, –2 to 16; $p = 0.12$) lower in the MRI group compared with the non-MRI group (Table 3). This difference was mainly due to a 13% (95% CI, 1–25; $p = 0.024$) lower rate of BNS in patients with cT2–3 (Fig. 4).

### 3.3. Overall risk of positive surgical margins

There were 49 cases (23%) of PSMs in the non-MRI group and 43 (19%) in the MRI group (Table 4). The relative and absolute reduction was 15% (0.85; 95% CI, 0.6–1.2) and 4% (95% CI, –4 to 10; $p = 0.4$), respectively. The number needed to treat was 25, and two extra nerve resections (1.7%) were performed for each PSM avoided.

### 3.4. Risk of positive surgical margins in patient subgroups

MRI did not reduce the rates of PSMs in cT2–3, whereas in cT1, the relative and absolute reduction was 41% (0.59; 95% CI, 0.4–0.9) and 11% (95% CI, 2–22; $p = 0.035$), respectively (Tables 3 and 4). There was no benefit of MRI in any other subgroups.

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**Table 2 – The performance of magnetic resonance imaging and digital rectal examination/transrectal ultrasound for detecting pT3 disease**

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity, % (95% CI)</th>
<th>Specificity, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MRI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All patients</td>
<td>73 (63–81)</td>
<td>65 (54–74)</td>
</tr>
<tr>
<td>cT1</td>
<td>56 (41–70)</td>
<td>70 (57–81)</td>
</tr>
<tr>
<td>cT2–3</td>
<td>88 (76–95)</td>
<td>55 (36–72)</td>
</tr>
<tr>
<td>DRE/TRUS</td>
<td>4 (2–8)</td>
<td>98 (95–99)</td>
</tr>
</tbody>
</table>

CI = confidence interval; DRE/TRUS = digital rectal examination/transurethral ultrasound; MRI = magnetic resonance imaging.
Rates of PSMs in patients with adjusted and nonadjusted surgery were 25% and 17%, respectively (8% difference; 95% CI, –4 to 22; \( p = 0.17 \)). Most patients with PSMs underwent UNS or NNS; 36 of 49 (73%) in the non-MRI group and 36 of 43 (84%) in the MRI group (11% difference; 95% CI, –8 to 23; \( p = 0.072 \)). For patients classified as rT3, the rate of PSMs was 25%; 89% of these patients underwent either UNS or NNS (Fig. 5).

3.5. Distribution of positive surgical margins and the associated tumour

There were 126 sites of PSMs in 92 specimens (Fig. 6). Sixty patients had a single PSM site; 32 had more than one. The index tumour was the responsible tumour in 89% of all cases of PSMs, and 60% were associated with EPE at the same location.

MRI detected 92% of all tumours related to PSMs. The base and apex were at higher risk for PSMs (Fig. 3). The risk of ventral PSMs in the apex was higher in the non-MRI group (12%; 95% CI, –3 to 23; \( p = 0.072 \)).

4. Discussion

The present study is the first RCT to evaluate the benefit of MRI prior to RALP. We could not demonstrate a significant reduction in the rate of PSMs for either the whole cohort or patients with pT3. However, we found a 41% lower rate of PSMs in patients with cT1 (\( p = 0.035 \)), although this was not statistically significant in the context of multiple testing. The rate of PSMs varies significantly in the literature, and our results are within acceptable limits [17,18].

4.1. Effect of magnetic resonance imaging on surgical approach

MRI changed the surgical strategy in 29%, all in the direction of more radical excision. Other studies have reported that MRI affected the surgery in a radical direction in only 33–39% [19–21]. None of these studies had a control arm without MRI, making comparison difficult.

Most of the patients with PSMs had undergone UNS or NNS in both the non-MRI and MRI group. Also, when MRI suggested T3, 89% of those with PSMs had undergone either

<table>
<thead>
<tr>
<th>Table 3 – Positive surgical margin rate with respect to surgical procedure, cT stage, and Gleason score in biopsy</th>
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<tbody>
<tr>
<td><strong>Non-MRI (n = 216)</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td>n</td>
</tr>
<tr>
<td>Bilateral nerve-sparing surgery</td>
</tr>
<tr>
<td>cT1</td>
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<tr>
<td>cT2–3</td>
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<tr>
<td>Gleason score in biopsy</td>
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<tr>
<td>6</td>
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<tr>
<td>7a</td>
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<td>7b</td>
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<tr>
<td>8</td>
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<tr>
<td>All patients</td>
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<tr>
<td>Unilateral nerve-sparing surgery</td>
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<td>cT1</td>
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<td>All patients</td>
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<td>Non–nerve-sparing surgery</td>
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<td>cT1</td>
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<td>cT2–3</td>
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<td>Gleason score in biopsy</td>
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<td>7a</td>
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<td>7b</td>
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<tr>
<td>8</td>
</tr>
<tr>
<td>9</td>
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<tr>
<td>All patients</td>
</tr>
</tbody>
</table>

DRE = digital rectal examination; MRI = magnetic resonance imaging; NA = not available; PSM = positive surgical margins.
* The \( p \) value for interaction.
UNS or NNS (Fig. 5). This suggests that even more extended excisions are required to reduce the rate of PSMs.

4.2. Rate of positive surgical margins in patients with cT1

Surprisingly, the greatest benefit of MRI was seen in patients with cT1. This was unexpected because the sensitivity of MRI for predicting pT3 in this group was poor (Table 2), and surgical procedures were not significantly different between the non-MRI and MRI group (Fig. 4). This suggests that the primary value of MRI was to provide the surgeon with accurate information about tumour location and extension, whereas staging was of secondary importance.

4.3. Possible mechanisms for improved outcome in cT1

This study cannot explain the exact mechanisms for the reduced rate of PSMs in patients with cT1. However, one possibility may be excellent tumour visualisation on MRI, also in patients with cT1, whereas DRE and TRUS are normal. This probably favours selection of the proper surgical procedure, and it may have prevented dissection too close to the index tumour or changed the surgery in ways not registered in this study. For instance, in case of a ventral cancer with extraprostatic disease, it is possible to perform a combination of BNS and extended excision ventrally.

4.4. Importance of the index tumour and positive surgical margins site

The index tumour was the source of PSMs in 89% of the cases (Fig. 6). This illustrates the relevance of locating the index tumour before surgery and is in accordance with a 2012 study [22]. However, despite the fact that MRI detected 98% of these tumours, the rate of PSMs did not improve for the whole cohort. If the MRI findings are

### Table 4 – Rate of positive surgical margins in the non–magnetic resonance imaging (MRI) and MRI groups

<table>
<thead>
<tr>
<th></th>
<th>Non-MRI (n = 216)</th>
<th>MRI (n = 222)</th>
<th>p</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>Total, n = 216</td>
<td>PSM, n = 49</td>
<td>%</td>
<td>23</td>
<td>0.4</td>
</tr>
<tr>
<td>DRE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cT1</td>
<td>114</td>
<td>31</td>
<td>27</td>
<td>25</td>
<td>0.035</td>
</tr>
<tr>
<td>cT2–3</td>
<td>102</td>
<td>18</td>
<td>18</td>
<td>18</td>
<td>0.3</td>
</tr>
<tr>
<td>D'Amico risk classification</td>
<td></td>
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<tr>
<td>Low</td>
<td>55</td>
<td>7</td>
<td>13</td>
<td>7</td>
<td>0.38</td>
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<tr>
<td>Medium</td>
<td>103</td>
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<td>23</td>
<td>24</td>
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<tr>
<td>High</td>
<td>58</td>
<td>18</td>
<td>31</td>
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<td>0.41</td>
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<tr>
<td>pT stage</td>
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<tr>
<td>3</td>
<td>105</td>
<td>40</td>
<td>38</td>
<td>32</td>
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<tr>
<td>Gleason score in specimen</td>
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<td>6</td>
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<td>0.58</td>
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<tr>
<td>9</td>
<td>7</td>
<td>3</td>
<td>43</td>
<td>2</td>
<td>0.44</td>
</tr>
</tbody>
</table>

CI = confidence interval; DRE = digital rectal examination; MRI = magnetic resonance imaging; OR = odds ratio. OR <1 indicates a reduced risk of positive surgical margins; OR >1 indicates an increased risk.

* The p value for interaction: A significant interaction p value indicates that the ORs of the subgroups are significantly different.
included in the planning of surgical approach to a larger extent, it represents a considerable potential for improvement in the future.

The MRI group experienced a lower rate of PSMs in the ventral apex (Fig. 3), although the prognostic value of this is controversial [23,24].

4.5. Magnetic resonance imaging protocol

This study used a simple MRI protocol, without contrast medium and endorectal coil, compared with the current European Society of Urogenital Radiology recommendation [25]. Nevertheless, we achieved similar detection and staging results as those who have used the current recommendation [2,4,5,26,27]. This may indicate that a simple protocol is truly sufficient, although no studies have compared the different protocols on the same cohort, and direct comparison of results is difficult. Alternatively, our high rate of large tumours with pT3 resulted in extraordinary results.

From a surgical point of view, it is critical to stress that MRI tumour detection is highly sensitive in most studies;
staging remains the weakest element. For this reason, urologists are encouraged to consider tumour location more than rT classification when deciding surgical strategy.

4.6. Limitations

This study has some possible limitations. First, the study was underpowered to demonstrate a significant effect of MRI because the observed rate of PSMs was approximately half of the expected rate. Because all subgroup analyses were not defined a priori, one should interpret the findings in cT1 with caution and instead conduct future studies. Second, more patients were referred to radiation therapy in the non-MRI group after randomisation. This may be an indicator of more advanced disease, likely to result in PSMs. Consequently, it may have reduced the effect of MRI. Third, the radiologist was not fully blinded to clinical data. This might have affected the MRI results and consequently patient handling. Fourth, there was suboptimal communication between the radiologist and the urologist during this study. This is probably the most important reason why the difference in the rate of PSMs between the two groups was not larger. We believe the radiologists and the urologist should co-investigate MRI images prior to surgery because only reading a written report or looking at a schematic drawing is suboptimal when planning surgery.

5. Conclusions

We showed that the index tumour, usually detected by MRI, is the most frequent cause of PSMs. We did not find an overall reduction in the rate of PSMs in patients randomised to MRI, although subgroup analysis revealed a possible benefit in patients with cT1. Our study suggests more radical resection should be performed in the index tumour region and that future studies should focus on MRI-guided RP. In the MRI group, slightly more nerve resections were performed, which can be considered a potential negative effect of MRI. More studies are needed to evaluate the role of MRI before prostatectomy.

Author contributions: Erik Rud had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Rud, Egggesbø, Eri.
Acquisition of data: Rud, Klotz, Svindland, Wessel, Berg, Berge, Hoff, Rennesund, Lundbey.
Analysis and interpretation of data: Rud, Eri, Baco.
Drafting of the manuscript: Rud, Eri, Baco.
Critical revision of the manuscript for important intellectual content: Rud, Eri, Baco, Egggesbø.
Statistical analysis: Rud, Diep.
Obtaining funding: None.
Administrative, technical, or material support: None.
Supervision: Rud, Egggesbø.
Other (specify): None.

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