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Bladder Cancer

# Robot-assisted Versus Open Radical Cystectomy in Bladder Cancer: An Economic Evaluation Alongside a Multicentre Comparative Effectiveness Study

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#### **Abstract**

**Background:** Open radical cystectomy (ORC) is regarded as the standard treatment for muscle-invasive bladder cancer, but robot-assisted radical cystectomy (RARC) is increasingly used in practice. A recent study showed that RARC resulted in slightly fewer minor but slightly more major complications, although the difference was not statistically significant. Some differences were found in secondary outcomes favouring either RARC or ORC. RARC use is expected to increase in coming years, which fuels the debate about whether RARC provides value for money.

**Objective:** To assess the cost-effectiveness of RARC compared to ORC in bladder cancer. **Design, setting, and participants:** This economic evaluation was performed alongside a prospective multicentre comparative effectiveness study. We included 348 bladder cancer patients (ORC, n = 168; RARC, n = 180) from 19 Dutch hospitals.

Outcome measurements and statistical analysis: Over 1 yr, we assessed the incremental cost per quality-adjusted life year (QALY) gained from both healthcare and societal perspectives. We used single imputation nested in the bootstrap percentile method to assess missing data and uncertainty, and inverse probability of treatment weighting to control for potential bias. Deterministic sensitivity analyses were performed to explore the impact of various parameters on the cost difference.

Results and limitations: The mean healthcare cost per patient was €17 141 (95% confidence interval [CI] €15 791–€18 720) for ORC and €21 266 (95% CI €19 163–€23 650) for RARC. The mean societal cost per patient was €18 926 (95% CI €17 431–€22 642) for ORC and €24 896 (95% CI €21 925–€31 888) for RARC. On average, RARC patients gained 0.79 QALYs (95% CI 0.74–0.85) compared to 0.81 QALYs (95% CI 0.77–0.85) for ORC patients, resulting in a mean QALY difference of -0.02 (95% CI -0.05 to 0.02). Using a cost-effectiveness threshold of €80 000, RARC was cost-effective in 0.6% and 0.2% of the replications for the healthcare and societal perspectives, respectively.

**Conclusions:** RARC shows no difference in terms of QALYs, but is more expensive than ORC. Hence, RARC does not seem to provide value for money in comparison to ORC. **Patient summary:** This study assessed the relation between costs and effects of robotassisted surgery compared to open surgery for removal of the bladder in 348 Dutch

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patients with bladder cancer. We found that after 1 year, the two approaches were similarly effective according to a measure called quality-adjusted life years, but robot-assisted surgery was much more expensive.

This trial was prospectively registered in the Netherlands Trial Register as NTR5362 (https://www.trialregister.nl/trial/5214).

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#### 1. Introduction

Currently, open radical cystectomy (ORC) and robotassisted radical cystectomy (RARC) are the two techniques most frequently used to perform radical cystectomy [1]. Various systematic reviews have compared RARC with ORC, but due to the low to moderate quality of the individual studies, no firm conclusions could be drawn [2–4].

A recent prospective multicentre comparative-effectiveness study did not show a statistically significant difference in complications between RARC and ORC [5]. Within 1 yr, RARC resulted in slightly fewer minor complications (risk difference -5.7%, 95% confidence interval [CI] -16.8% to 5.3%), but slightly more major complications (risk difference 3.3%, 95% CI -5.9% to 12.1%) [5]. Analyses showed no differences in health-related quality of life (HRQOL). Some differences were found in secondary outcomes favouring either RARC or ORC. Given the small but different benefitrisk profiles in combination with opposed preferences of clinicians regarding evidentiary requirements, it is expected that the use of RARC will further increase in coming years. This fuels the debate on whether such an increase in the use of RARC provides value for money. The direct costs of robotic surgery are high, and questions on whether these are outweighed by the benefits become increasingly relevant. In addition, considering the rising demand for healthcare and increased attention on sustainable healthcare, it is important to assess the added value of an intervention against its direct and indirect costs in order to justify its use to society. Alongside the comparative effectiveness study, data were collected on healthcare and societal costs. The aim of this study was to assess the cost-effectiveness of RARC compared to ORC for patients with bladder cancer (BCa) in order to inform the development of evidence-based guidelines.

## 2. Patients and methods

## 2.1. Design, setting, and participants

We conducted an economic evaluation alongside a prospective multicentre comparative-effectiveness study in four tertiary and 15 secondary referral hospitals in The Netherlands. This economic evaluation is reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards guideline [6]. The comparative effectiveness study protocol was previously published [7] and the medical ethics committee of Radboud University Medical Center (Nijmegen, The Netherlands) determined that the study does not fall under the scope of the Medical Research Involving Human Subjects Act.

Patients were included if they were aged  $\geq$ 18 yr and had histologically proven primary muscle-invasive urothelial carcinoma (cT2a-4a,

NOM0) with or without neoadjuvant chemotherapy, or therapy-resistant high-risk non–muscle-invasive BCa (carcinoma in situ or refractory pTa–1) [7]. We excluded patients if they had postchemotherapy radiologically proven node-positive disease, previous major abdominal surgery (existing stomata, low anterior resection of the rectum or rectal amputation, open aortobifemoral graft, or right hemicolectomy), were morbidly obese (body mass index  $\geq$ 40 kg/m²), were pregnant, or if they had undergone RC in combination with nephrectomy or partial colon resection. Written informed consent was obtained from all patients. Patients entered the nearest hospital and urologists did not select a technique on the basis of patient or tumour characteristics. Eight centres performed RARC, nine centres performed ORC, and two of the participating centres performed both techniques [5,7].

## 2.2. Measures of effectiveness

We used two measures of effectiveness: quality-adjusted life years (QALYs) and the rate of complications (according to the Clavien-Dindo grading). Complications of any grade (grades 1–5) [8] were registered within 30 d, 90 d, and 365 d after cystectomy in a central validated database (eCRF, Research Manager) by (local) clinicians. To derive QALYs, HRQOL was measured using the EuroQol 5-Domain 5-Level (EQ-5D-5L) questionnaire [9], which was administered at baseline, 30 d, 90 d, 180 d, and 365 d, and utility scores were calculated using the Dutch value set [10]. On the basis of these utility scores, QALYs were computed using the area under the curve approach [11].

#### 2.3. Costs

The economic evaluation was conducted from both healthcare and societal perspectives. The healthcare perspective includes healthcare costs for treatment and follow-up (eg, medication use, interventions, imaging). The societal perspective additionally includes relevant nonhealthcare costs such as travel expenses, home care, and productivity losses [12]. Costs were estimated by multiplying the resource use by the corresponding (list) price. Resource use was prospectively collected from clinician-reported medical data and patient-reported cost questionnaires. Clinicians registered medical data covering resources related to surgery (operation equipment, skin-to-skin operating time, blood transfusions, number of surgeons, total parenteral nutrition), hospital stay (intensive care, medium care, hospital department), complications (interventions, additional imaging, additional hospitalisation), and recurrences (diagnosis, treatment). Patients registered other resource use on the basis of two cost questionnaires for medical consumption and productivity costs [13,14]. Each month, patients recorded the number of resources used for BCa complaints, such as medication use, appointments with their general practitioner, kilometres travelled, hours of work lost, and hours of informal care needed. Parking costs were obtained directly from the cost questionnaire. Total costs were calculated by multiplying the number of resources used by the corresponding unit cost.

Costs associated with the da Vinci robot (Intuitive Surgical Inc., Sunnyvale, CA, USA) were calculated in accordance with the Dutch guideline for economic evaluation [12]. Costs were based on the

purchase list price (€1.7 million), an interest rate of 4.3%, annual depreciation costs over a 7-yr depreciation period, and annual maintenance costs. To derive fixed robotic costs per patient, we assumed an average of 280 annual surgeries per robot system [15]. In addition, costs for fixed RARC equipment (eg, drapes, tip cover accessory), variable RARC equipment (eg, robotic instruments, staplers), and variable ORC equipment (eg, LigaSure, staplers) were based on the list price. We excluded the costs of preoperative care. Reference costs for medical contacts, hours of informal care, hours of work lost, and travel expenses were based on the Dutch guideline [12]. Cost prices for medication were derived from the Dutch formulary, from which we used list prices [16]. Costs for complications (interventions, additional imaging) and recurrences (ie, diagnosis, treatment) were based on the Dutch Healthcare Authority [17] and cost prices in Radboud University Medical Center (Nijmegen, The Netherlands) and Rijnstate Hospital (Arnhem, The Netherlands). All costs were converted to the 2019 price level using consumer price indices

[18]. An overview of the resources used and corresponding cost prices are presented in the Supplementary material.

#### 2.4. Statistical analysis

Absolute means and mean differences between RARC and ORC for costs, complications, and QALYs over 1 yr were calculated. In accordance with the Professional Society for Health Economics and Outcomes Research (ISPOR) guidelines, we reported mean cost values [19]. If RARC was more costly and more effective, or if RARC was less costly and less effective, we calculated an incremental cost-effectiveness ratio (ICER). ICERs were calculated by dividing the estimated cost difference by the difference in the rate of complications and QALYs. ICERs thus represent the extra costs to prevent the incidence of one patient with a complication (any grade) and the extra costs to gain 1 QALY. Following the Dutch guideline for economic evaluation, we used a cost-effectiveness threshold of €80 000 per OALY [12].

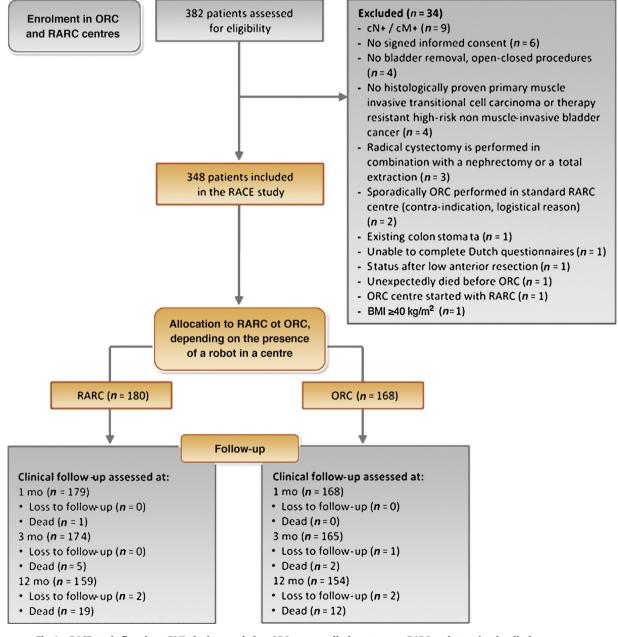


Fig. 1 - RACE study flowchart. BMI = body mass index; ORC = open radical cystectomy; RARC = robot-assisted radical cystectomy.

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Table 1 - Patient characteristics of the weighted study population <sup>a</sup>

| Characteristic                                  | ORC              | RARC             |
|---|------------------|------------------|
| Median age, yr (IQR)                            | 69.0 (60.4–75.0) | 68.0 (63.0-73.0) |
| Males (%)                                       | 77.9             | 78.0             |
| Median body mass index, kg/m <sup>2</sup> (IQR) | 26.2 (24.4–29.2) | 26.5 (23.7-28.8) |
| Median Charlson comorbidity index, points (IQR) | 5.2 (4.0-6.4)    | 5.5 (3.9-6.4)    |
| American Society of Anesthesiologists score (%) |                  |                  |
| 1   | 11.1             | 11.4             |
| 2   | 65.0             | 64.9             |
| 3   | 22.8             | 22.7             |
| 4   | 1.0              | 1.0              |
| Diversion type (%)                              |                  |                  |
| Ileal conduit                                   | 82               | 81               |
| Neobladder/pouch                                | 16               | 17               |
| No bowel  | 2                | 2.1              |

IQR = interquartile range; ORC = open radical cystectomy; RARC = robot-assisted radical cystectomy.

As recommended by Brand et al [20], the effect of missing data was assessed using the method of single imputation nested in the bootstrap percentile. First, bootstrapping was used to generate 5000 incomplete data sets, and then a single completed data set was generated for every incomplete data set. Second, considering the comparative effectiveness design, we used inverse probability of treatment weighting (IPW) to account for potential confounders [21]. The Supplementary material presents a detailed description of the analyses. Using the bootstrapping results, 95% CIs and cost-effectiveness acceptability curves were derived to illustrate the probability of cost-effectiveness against different costeffectiveness thresholds. To explore the impact of specific cost categories on the additional costs of RARC, deterministic sensitivity analyses were performed [22]. The following parameters were varied: cost of complications for RARC, length of hospital stay for RARC, annual robotic surgeries per hospital, robot purchase price, paid home care, and family help. Data were managed using SPSS v25.0 (IBM Corp., Armonk, NY, USA), Microsoft Excel 2016 (Microsoft Corporation, Redmond, WA, USA), and R v3.6.3 (R Foundation for Statistical Computing, Vienna, Austria).

#### 3. Results

#### 3.1. Participant characteristics

A total of 348 patients (ORC, n = 168; RARC, n = 180) were included in the study (Fig. 1). The unweighted baseline characteristics were generally similar between the ORC and RARC groups, with a few exceptions. After IPW, all baseline characteristics were well balanced between the treatment groups [5]. Patient characteristics of the IPW-adjusted population are presented in Table 1. Within 1 yr, 67% of ORC and 64% of RARC patients experienced at least one complication (any grade), resulting in a difference of -3.3% (95% CI -14% to 7.2%). Some perioperative differences were found between the two techniques, favouring either RARC or ORC (Table 2).

Table 2 - Overview of IPW-adjusted complications according to the Clavien-Dindo classification and perioperative outcomes a

|   |               | IPW population |                                   |
|---|---------------|----------------|-----------------------------------|
|   |               |                |                                   |
|   | ORC           | RARC           | Difference (95% CI)               |
| Complications from 0 to 365 d               |               |                |                                   |
| Any complication (grade 1-5) (%)            | 67            | 64             | -3.3 (-14 to 7.2)                 |
| Minor complication (grade 1-2) (%)          | 61            | 55             | -5.7 (-17 to 5.3)                 |
| Major complication (grade 3-5) (%)          | 20            | 23             | 3.1 (-5.9 to 12)                  |
| Perioperative outcomes                      |               |                |                                   |
| Median estimated blood loss, ml (IQR)       | 600 (400-950) | 300 (150-400)  | -403 (-507 to -299) b             |
| Perioperative transfusion (%)               | 14            | 9.2            | -4.7 (-12 to 2.0)                 |
| Median packed cell units (IQR)              | 2 (2.0-2.0)   | 2 (1.9-2.0)    | 0.5 (-0.4 to 1.3) b               |
| Median hospital stay, d (IQR)               | 11 (9–14)     | 8 (7-11)       | $-2.4~(-4.1~{ m to}~-0.6)^{ m b}$ |
| ICU admission (%)                           | 48            | 25             | −24 (−34 to −13)                  |
| Median ICU stay, d (IQR)                    | 1 (1-1)       | 1 (1-1)        | 0.9 (-0.6 to 2.4) b               |
| Median total operating room time, min (IQR) | 267 (208-320) | 401 (335-478)  | 145 (121 to 168) <sup>b</sup>     |
| TPN (%)                                     | 33            | 16             | −17 (−27 to −7.5)                 |
| Median TPN duration, d (IQR)                | 8 (6-10)      | 7 (4.6–10)     | -1.5 (-4.2 to 1.3) b              |
| Adjuvant chemotherapy (%)                   | 8.1           | 3.5            | -4.6 (-9.7 to 0.5)                |
| Mortality at 365 d (%)                      | 12            | 14             | 2.1 (-5.2 to 9.5)                 |
| Recurrence at 365 d (%)                     | 25            | 24             | -1.1 (-11 to 8.4)                 |

CI = confidence interval; ICU = intensive care unit; IPW = inverse probability weighted; IQR = interquartile range; ORC = open radical cystectomy; RARC = robot-assisted radical cystectomy; TPN = total parenteral nutrition.

<sup>&</sup>lt;sup>a</sup> A complete overview of patient characteristics is presented in Wijburg et al [5].

<sup>&</sup>lt;sup>a</sup> A complete overview of the patient characteristics is presented in Wijburg et al [5]. Effect sizes were assessed as risk differences and were calculated as RARC arm – ORC arm.

b Effect size assessed as mean difference.

Table 3 - Mean healthcare and societal costs per patient for ORC and RARC over 1-yr follow-up

| Cost category                     |                        | Mean cost, € (95% CI)  |                      |  |
|-----------------------------------|------------------------|------------------------|----------------------|--|
|                                   | ORC                    | RARC                   | Mean difference      |  |
| Surgery <sup>a</sup>              | 4742 (4480–5015)       | 8880 (8605–9151)       | 4139 (3747-4515)     |  |
| Complications <sup>a</sup>        | 2397 (1730-3273)       | 3675 (2342-5199)       | 1279 (302-2875)      |  |
| Hospital stay <sup>a</sup>        | 7974 (7277–8793)       | 6645 (5575–8154)       | -1329 (-2716 to 288) |  |
| Recurrences <sup>a</sup>          | 1085 (555–1714)        | 1037 (455–1798)        | -48 (-885 to 842)    |  |
| Health care contacts <sup>b</sup> | 797 (600–1079)         | 860 (637-1304)         | 63 (-174 to 445)     |  |
| Medication use <sup>b</sup>       | 147 (78–241)           | 169 (88–250)           | 21 (-94 to 120)      |  |
| Total healthcare costs            | 17 141 (15 791–18 720) | 21 266 (19 163-23 650) | 4125 (1471-6722)     |  |
| Travel expenses b                 | 115 (69–183)           | 90 (59–135)            | -25 (-92 to 34)      |  |
| Productivity losses b             | 502 (218-853)          | 496 (292-1137)         | -6 (-258 to 646)     |  |
| Paid home care and family help b  | 1169 (825-4,279)       | 3043 (1297-8892)       | 1875 (-98 to 6469)   |  |
| Total societal costs              | 18 926 (17 431-22 642) | 24 896 (21 925-31 888) | 5969 (2357-11 841)   |  |

CI = confidence interval; ORC = open radical cystectomy; RARC = robot-assisted radical cystectomy.

#### 3.2. Costs

The mean component cost and mean total costs per patient from both healthcare and societal perspectives are shown in Table 3. From a healthcare perspective, the mean cost per patient was €17 141 (95% CI €15 791 – €18 720) for ORC and €21 266 (95% CI €19 163 – €23 650) for RARC, resulting in a mean cost difference of €4125 (95% CI €1471 – €6722). From a societal perspective, the mean cost per patient was €18 926 (95% CI €17 43 – €22 642) for ORC and €24 896 (95% CI €21 925 – €31 888) for RARC. The mean societal cost for RARC was €5969 (95% CI €2357 – €11 841) higher than for ORC, mainly because of the robotic system, surgery costs, home care and family help, and complication costs.

# 3.3. Costs per prevented incidence of a patient with a complication

Within 1 yr of follow-up, 64% of RARC and 67% of ORC patients experienced a complication of any grade (Table 4). From a healthcare perspective, the extra cost to prevent the incidence of one patient with a complication of any grade with RARC compared to ORC was €112 125. From a societal perspective, the incremental cost to prevent the incidence

of one RARC patient with a complication of any grade in comparison to ORC was €162 253.

#### 3.4. Costs per QALY

On average, RARC patients gained 0.79 QALYs (95% CI 0.74–0.85), compared to 0.81 QALYs (95% CI 0.77–0.85) for ORC patients (Table 4). The mean QALY difference was -0.02 QALYs (95% CI -0.05 to 0.02). From both the healthcare and social perspectives, RARC is more costly and shows no difference in effectiveness, and was thus dominated by ORC (Fig. 2).

RARC was cost-effective in 0.6% (healthcare perspective) and 0.2% (societal perspective) of the replications using a cost-effectiveness threshold of €80 000 per QALY (Fig. 3).

Deterministic sensitivity analyses showed that when the robot purchase price was reduced by 50% (€850 000), RARC was €3673 more expensive per patient than ORC from a healthcare perspective. From a societal perspective, RARC was €5518 more expensive per patient than ORC. In addition, when other parameters were varied (costs of complications, length of hospital stay, annual robotic surgeries per hospital, robot purchase price, and paid home care and family help), RARC was dominated by ORC. Results from

Table 4 – Absolute means and incremental differences between RARC and ORC in costs, complications, and QALYs over 1-yr follow-up from a from healthcare and a societal perspective

|  | Health care costs      |                        | Societal costs         |                        |
|--|------------------------|------------------------|------------------------|------------------------|
|  | ORC                    | RARC                   | ORC                    | RARC                   |
| Mean cost per strategy, € (95% CI)                         | 17 141 (15 791–18 720) | 21 266 (19 163-23 650) | 18 926 (17 431-22 642) | 24 896 (21 925-31 888) |
| Incremental cost, € (95% CI)                               | -                      | 4125 (1471-6722)       | -                      | 5969 (2357-11 841)     |
| Effectiveness, QALYs (95% CI)                              | 0.81 (0.77-0.85)       | 0.79 (0.74-0.85)       | 0.81 (0.77-0.85)       | 0.79 (0.74-0.85)       |
| Incremental QALYs (95% CI)                                 | -                      | -0.02 (-0.05 to 0.02)  | -                      | -0.02 (-0.05 to 0.02)  |
| ICER (€/per QALY)  | -                      | RARC dominated by ORC  | -                      | RARC dominated by ORC  |
| Probability of a complication, % (95% CI)                  | 67 (59-75)             | 64 (56-71)             | 67 (59–75)             | 64 (56-71)             |
| Increment in risk of a complication, % (95% CI)            | -                      | -4 (-14 to 7)          | -                      | -4 (-14 to 7)          |
| ICER (€/per patient with a complication prevented in 1 yr) | -                      | 112 124                | -                      | 162 253                |

CI = confidence interval; ICER = incremental cost-effectiveness ratio; ORC = open radical cystectomy; QALY = quality-adjusted life years; RARC = robot-assisted radical cystectomy.

<sup>&</sup>lt;sup>a</sup> Resource use reported by clinicians.

<sup>&</sup>lt;sup>b</sup> Resource use reported by patients.

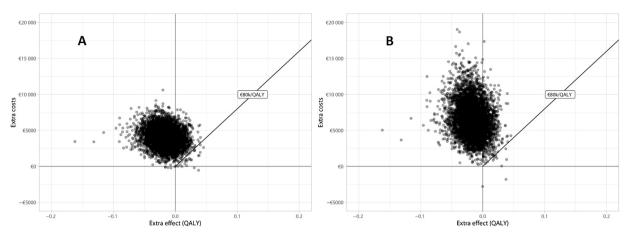


Fig. 2 – Cost-effectiveness plane of incremental costs in  $\in$  (*y*-axis) per quality-adjusted life year (QALY) gained (*x*-axis) for each of the bootstrap replications from (A) a healthcare and (B) a societal perspective after 1 yr.

the healthcare and societal perspectives are presented in separate tornado diagrams in the Supplementary material.

### 4. Discussion

This economic evaluation, performed alongside a prospective multicentre comparative-effectiveness study, showed no difference in QALYs, but RARC was more expensive than ORC. This implies that RARC is dominated by ORC. RARC resulted in fewer patients with complications than ORC. The extra healthcare cost needed to prevent the incidence of one patient with a complication of any grade was €112 124,

while this was €162 253 from a societal perspective. On the basis of the cost acceptability curves it seems unlikely that RARC will become cost-effective in comparison to ORC.

This study shows that the cost difference between RARC and ORC is mainly caused by the high cost of the robot system, surgery costs, home care and family help, and complication costs. RARC resulted in higher costs partly because of the occurrence of relatively more major complications, which are associated with high treatment costs.

Most previous cost(-effectiveness) studies also reported that RARC was associated with higher costs [23–28]. Most of these studies could not publish the exact cost data for

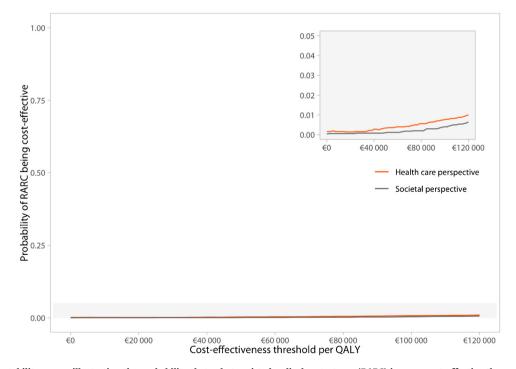


Fig. 3 – Cost acceptability curves illustrating the probability that robot-assisted radical cystectomy (RARC) is more cost-effective than open radical cystectomy from a healthcare perspective and a societal perspective at different cost-effectiveness thresholds. The inset shows a magnification of the curves from 0.00 to 0.05 on the y-axis. Using a threshold of  $\in$ 80 000 per quality-adjusted life year (QALY), RARC was cost-effective in 0.6% and 0.2% of the replications from the healthcare and societal perspectives, respectively, after 1 yr.

proprietary reasons, which limits a direct comparison. One cost-effectiveness model using data from a retrospective single-centre cohort and QALY assumptions based on literature data showed that RARC was associated with an increase in QALYs [26], which does not correspond with our findings.

The main strength of this study is that it is the first trial-based economic evaluation of RARC compared to ORC. Data on costs and effects were prospectively and simultaneously collected in a multicentre comparative effectiveness study, covering both healthcare and societal perspectives. As we performed a comparative effectiveness study, real-world data were used in this economic evaluation, which thus results reflect the actual cost-effectiveness in Dutch clinical practice.

Some of our findings deserve further attention. First, as the data are derived from a multicentre pragmatic study design, which strengthens the economic evaluation, a different approach than a traditional randomised controlled trial was required. For instance, we addressed confounding by indication by performing IPW analyses with pretreatment variables. It has been shown that IPW provides valid estimates [21]. Second, the follow-up period is limited to 1 yr. Since we did not find differences in recurrence or mortality rates after 1 yr [5], we expect that longer follow-up would not provide new insights regarding QALYs and cost-effectiveness.

Third, every 3 mo approximately 40% of the data from the patient-reported questionnaires were missing at a domain level. Therefore, we assessed the effect of missing data using single imputation nested in the bootstrap percentile, as recommended by Brand et al [20]. This method has the most favourable statistical properties for handling missing and skewed cost-effectiveness data [20].

Fourth, we used list prices for medication and the da Vinci robot. We are aware that some centres might pay less because of individual agreements with companies. Regarding robot costs, sensitivity analyses showed that even with a robot purchase price reduction of 50% (€850 000), RARC would not become cost-effective. Regarding medication costs, we did not incorporate costs of preparation for administration, so the total medication costs might be underestimated; however, medication usage was comparable between the two groups.

Fifth, RARC patients used more home care and family help, which predominantly occurred in the first 3 mo. We found some RARC patients with outlier values for home care and family help. When these RARC outliers were excluded, the difference in costs was smaller, but this would not affect the conclusion. Although Hu et al [25] also reported greater use of home care by RARC patients, it could be a coincidence that our outliers only occurred in the RARC group, as we cannot firmly explain the difference observed.

Finally, we did not measure or include the potential ergonomic advantages, an argument often used for surgical robots. Both the ergonomics itself and the potential associated loss of surgeon productivity are difficult to measure and were therefore excluded from this analysis. Furthermore, considering the large cost difference between RARC

and ORC, we do not expect that including ergonomics would change our results.

#### 4.1. Clinical and policy implications

This study showed a mean QALY difference of -0.02 QALYs (95% CI -0.05 to 0.02) when comparing RARC to ORC, corresponding to a loss of 7 d in full health. With a QALY difference of -0.02. RARC needs to save €1600 to meet the threshold of €80 000. With a societal cost difference of €5969, RARC should result in a gain of 0.07 QALYs to meet the threshold of €80 000 when compared to ORC. Although many Dutch hospitals have already switched to RARC, partly because of the general idea among stakeholders that RARC is at least as effective as ORC, this study shows a small difference in complications and QALYs. With this study, we aim to inspire a debate between stakeholders as a first step towards evidence-based policy development. One of the issues that needs to be addressed is the high cost of RARC. In this study we assessed the mean cost per patient, which does not yet inform the economic impact of using RARC for society. Therefore, we assessed the budget impact for 5 yr and took into account that approximately 300 RARC and 700 ORC procedures are performed annually in The Netherlands [29,30]. From a societal perspective, if all RARC procedures were switched back to ORC and ORC became the standard technique in clinical practice, Dutch society would save €8 954 000 over a period of 5 yr without compromising HRQOL. Urologists, patients, and other stakeholders should be aware of this economic impact of using RARC.

In light of our findings, it seems unjustified that RARC is broadly implemented in clinical practice, since it does not provide value for money. As long as RARC is not more effective than ORC, our advice is not to encourage a further transition from ORC to RARC. At the same time, we must acknowledge that many robots are already installed and that de-implementation seems unrealistic. Besides, hospitals and urologists may have different motives for using the robotic approach [31]. If future studies observe that RARC is more effective than ORC in terms of HRQOL, health economic models can be used to update the cost-effectiveness results.

#### 5. Conclusions

This Dutch comparative effectiveness study shows no difference in HRQOL between RARC and ORC, but RARC is more expensive than ORC. This implies that RARC does not provide value for money in comparison to ORC.

**Author contributions:** Charlotte T.J. Michels 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: Grutters, Rovers, Wijburg, Witjes.

Acquisition of data: Michels, Wijburg.

Analysis and interpretation of data: Michels, Wijburg, Hannink, Witjes, Rovers, Grutters.

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Critical revision of the manuscript for important intellectual content: Michels, Wijburg, Hannink, Witjes, Rovers, Grutters.

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Supervision: Grutters, Rovers, Witjes.

Other: None.

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### Appendix B. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.euf.2021.06.004.

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