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Prostate Cancer

Inguinal Hernia After Radical Prostatectomy for Prostate Cancer: Results From a Randomized Setting and a Nonrandomized Setting

Johan Stranne[a,b,*], *Eva Johansson*[a,d,#], *Andreas Nilsson*[c,#], *Anna Bill-Axelson*[a,d], *Stefan Carlsson*[c], *Lars Holmberg*[e], *Jan-Erik Johansson*[f], *Tommy Nyberg*[a], *Mirja Ruutu*[g], *N. Peter Wiklund*[c], *Gunnar Steineck*[a,h]

[a] *Department of Oncology and Pathology, Division of Clinical Cancer Epidemiology, Karolinska Institute, Stockholm, Sweden*
[b] *Department of Urology, Sahlgrenska University Hospital, Gothenburg, Sweden*
[c] *Department of Molecular Medicine and Surgery, Division of Urology, Karolinska Institute, Stockholm, Sweden*
[d] *Department of Urology, Uppsala University Hospital, Uppsala, Sweden*
[e] *King's College, London School of Medicine, Division of Cancer Studies, London, UK*
[f] *Department of Urology, Örebro University Hospital, Örebro, Sweden*
[g] *Helsinki University Hospital, Department of Urology, Helsinki, Finland*
[h] *Division of Clinical Cancer Epidemiology, Department of Oncology, Institute of Clinical Sciences, Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden*

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Abstract

Background: Observational data indicate that retropubic radical prostatectomy (RRP) for prostate cancer (PCa) may induce inguinal hernia (IH) formation. Little is known about the influence of robot-assisted radical prostatectomy (RALP) on IH risk.
Objective: To compare the incidence of IH after RRP and RALP to that of nonoperated patients with PCa and to a population control.
Design, setting, and participants: We studied two groups. All 376 men included in the Scandinavian Prostate Cancer Group Study Number 4 constitute study group 1. Patients were randomly assigned RRP or watchful waiting (WW). The 1411 consecutive patients who underwent RRP or RALP at Karolinska University Hospital constitute study group 2. Men without PCa, matched for age and residence to each study group, constitute controls.
Measurements: Postoperative IH incidence was detected through a validated questionnaire. The participation rates were 82.7% and 88.4% for study groups 1 and 2, respectively.
Results and limitations: The Kaplan-Meier cumulative occurrence of IH development after 48 mo in study group 1 was 9.3%, 2.4%, and 0.9% for the RRP, the WW, and the control groups, respectively. There were statistically significant differences between the RRP group and the WW and control groups, but not between the last two. In study group 2 the cumulative risk of IH development at 48 mo was 12.2%, 5.8%, and 2.6% for the RRP, the RALP, and the control group, respectively. There were statistically significant differences between the RRP group and the RALP and control groups, but not between the last two.
Conclusions: RRP for PCa leads to an increased risk of IH development. RALP may lower the risk as compared to open surgery.

[#] Authors contributed equally.
[*] Corresponding author. Department of Urology, Sahlgrenska University Hospital, SE-413 45 Gothenburg, Sweden. Tel. +46 31 342100; Fax: +46 31 821740.
E-mail address: johan.stranne@vgregion.se (J. Stranne).

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1. Introduction

In 1996, Regan and coworkers suggested inguinal hernia (IH) as a postoperative complication of retropubic radical prostatectomy (RRP) performed through a lower midline incision [1]. Later reports indicate IH incidence of 12–21% within 2–3 yr after RRP and the lower midline incision per se is suggested to be causative [2–7]. However, we lack evidence from a prospective randomized study with long-term follow-up proving IH as a complication of RRP. Furthermore, we do not know if laparoscopic radical prostatectomy, in which smaller incisions in the lower abdominal region are used, lowers the risk.

We used a study-specific, face-to-face validated questionnaire in two different settings to investigate the incidence of IH after RRP and robot-assisted laparoscopic radical prostatectomy (RALP). The same questionnaire was also used for men with prostate cancer (PCa) treated without initial surgery (WW) and matched controls of men without PCa for comparison.

2. Patients and methods

2.1. Study group 1: Inguinal hernia after retropubic radical prostatectomy

Study group 1 (group 1) was composed of all 400 Swedish and Finnish living men who were prospectively included in the Scandinavian Prostate Cancer Group Study Number 4 (SPCG-4) between January 1, 1989, and February 28, 1999 [8], and alive in 2006. Inclusion criteria for the SPCG-4 trial included age <75 yr and a newly diagnosed, localized T0d, T1, or T2 tumor according to the 1978 criteria of the International Union Against Cancer [9]. After 1994, men with T1c tumors, according to the revised criteria of 1987, were also accepted [10]. The tumor had to be well to moderately well differentiated according to the definition established by the World Health Organization on the basis of a core biopsy or needle aspiration. Prostate-specific antigen (PSA) level had to be <50 ng/ml. A negative bone scan, a health status that would permit a radical prostatectomy, and a life expectancy of >10 yr was also required [11].

Each man was randomly assigned to undergo RRP or WW by a telephone service outside the clinics. For men randomized to RRP, the surgical procedure started with frozen sections of the regional lymph nodes; only if the lymph nodes were tumor free was an RRP performed based on the Walsh-Lepor technique [12].

Hormonal treatment was recommended for local, histologically verified recurrence in the RRP group and for disseminated disease in both groups. In the WW group, transurethral resection was recommended for urinary obstruction.

The SPCG-4 study was approved by the appropriate ethics committees.

2.2. Study group 2: Inguinal hernia after retropubic radical prostatectomy/robot-assisted laparoscopic radical prostatectomy

Study group 2 (group 2) was composed of 1411 consecutive patients who underwent radical prostatectomy at Karolinska University Hospital between January 2002 and December 2006. Of these, 465 were RRP based on the Walsh-Lepor technique [12], and 946 were RALP using the technique described by Nilsson and coworkers in 2006 [13]. None of the procedures included intraoperative IH repair. The technique of abdominal wall closure for the RRP was by continuous 0-0 monofilament loop in the fasciae and staples in the skin. All patients were admitted to the same urologic ward; the procedures were performed at the same operation ward and, in a majority of cases, by the same urologists. The study was approved by the local ethics committee.

Data were prospectively recorded on all patients regarding surgical technique, preoperative PSA, prostate volume, postoperative Gleason score, and pathologic T stage. No records were kept on the presence, if any, of subclinical IH found during prostatectomy.

2.3. Method of inguinal hernia detection

After an introductory letter and contact by telephone, the patients who agreed to participate in a quality-of-life follow-up were mailed a questionnaire. The assistant who made all the phone calls was unaware of the allocation of the patients. We developed the questionnaire on the basis of interviews with patients, tested it for face validity on 30 men, and further validated it in a small pilot study. The questionnaire was based on instruments previously used by our group [14,15] and consisted of 141 questions. Information was collected on potential confounding and effect-modifying factors (eg, previous surgery, comorbidity, medical treatments, and social factors). Concerning hernia, we asked the following questions:

- "Have you a hernia now, or have you had a hernia?"
- "When did you first notice that you had a hernia?"
- "Have you had surgery for hernia?"
- "Where on your body have you now or have you had a hernia?"

The last question had five alternative answers: "inguinal hernia," "scrotal hernia," "umbilical hernia," "incisional hernia," and "other hernia, please specify." All patients who answered the first question affirmatively were included in the analysis. Of these patients, those who also answered "inguinal hernia" on the last question and gave a date of hernia occurrence that was after inclusion in SPCG-4, or, in the case of group 2, after surgery, were registered as having an IH during follow-up. The questions were identical for both study groups. We collected the data for group 1 throughout 2006 and in the beginning of 2007; data for group 2 were collected during 2007. A question on height and weight was included in the questionnaire for group 2 but not for group 1. Body mass index (BMI) was calculated from these data (weight/height [m^2]).

We retrieved age-matched controls from the population registry, and the controls received identical questions concerning hernia. To compare IH development between patients and controls, the dates on which-follow-up was initiated for controls were hot-deck imputed using a patient from the same year of birth as donor for each control in each respective study group.

2.4. Statistical analysis

We followed the intention-to-treat principle for group 1. Kaplan-Meier survival analysis was used to estimate the cumulative IH-free survival for each group. The cumulative occurrence of developing a postoperative IH was calculated and plotted as 1 minus cumulative IH-free survival. Due to a much longer total follow-up for group 1, we calculated the cumulative occurrence of IH development with 95% confidence intervals (CIs) at 48 mo after inclusion/operation as well as at end of follow-up for comparison between the groups. CIs were estimated with the log-log transformation method. Log-rank (Mantel-Cox) test was used to explore differences in IH development between the groups. The hazards ratio (HR) of IH development for investigated factors and influence of potential effect-modifying/confounding factors was estimated from the univariable and multivariable Cox proportional hazards model. All tests were performed at the 5% significance level. The statistical analyses were carried out using the SPSS v.17 software package (SPSS Inc, Chicago, IL, USA).

Table 1 – Participation rates and demographic, physical, and oncologic characteristics of the patients in the study groups 1 and 2 and their respective control groups

Characteristics	Study group 1			Study group 2		
	Open prostatectomy	Watchful waiting	Population control	Open prostatectomy	Robot-assisted prostatectomy	Population control
Eligible patients, No.	208	192	281	465	946	442
Questionnaires returned, No. (%)	182 (87.5)	167 (87.0)	214 (76.2)	424 (91.2)	864 (91.3)	350 (79.0)
Age at randomization/surgery, yr						
Mean	64.2	65.2	60.0	63.0	61.9	60.2
Median	64.6	65.3	59.4	62.9	62.2	59.4
Range	49.3–75.0	45.1–74.7	48.3–74.7	46.7–77.6	36.7–77.5	47.2–75.4
Age at questionnaire, yr						
Mean	76.6	77.5	72.7	66.2	63.9	63.4
Median	77.1	77.9	71.5	66.2	64.2	62.8
Range	63.4–87.2	61.0–88.6	63.6–86.5	48.7–79.2	4.3–78.8	48.8–77.9
Follow-up time, mo						
Mean	148.9	147.0	152.9	38.3	23.6	38.7
Median	146.9	144.5	151.8	39.7	20.3	36.5
Range	95.0–205.1	93.2–202.7	96.3–218.0	3.7–64.0	4.6–63.2	14.7–75.9
BMI						
Mean	NA[1]	NA[1]	NA[1]	26.6	25.8	26.1
Median	NA[1]	NA[1]	NA[1]	26.2	25.5	25.7
Range	NA[1]	NA[1]	NA[1]	17.7–58.6	17.7–58.3	16.1–48.5
Comorbidity, No. (%)	17 (9)	21 (13)	23 (11)	137 (32)	202 (23)	98 (28)
Civil status, No. (%)						
Married or spouse	142 (78)	117 (70)	156 (73)	313 (74)	670 (78)	227 (65)
Living alone without partner	14 (8)	13 (8)	17 (8)	38 (9)	67 (8)	67 (19)
Living alone with occasional partner	8 (4)	11 (7)	17 (8)	22 (5)	53 (6)	28 (8)
Widower	16 (9)	21 (13)	21 (10)	13 (3)	10 (1)	7 (2)
Employment status, No. (%)						
Employed	3 (2)	3 (2)	20 (9)	143 (34)	429 (50)	182 (56)
Old-age pensioner	176 (97)	160 (96)	185 (86)	258 (61)	383 (44)	130 (37)
Long-term sick leave	0 (0)	0 (0)	5 (2)	4 (1)	16 (2)	5 (2)
Disability pension	0 (0)	1 (1)	4 (2)	15 (4)	22 (3)	9 (3)
Highest education, No. (%)						
Primary school (9 yr)	93 (51)	94 (56)	101 (47)	81 (19)	118 (14)	63 (18)
Secondary school (3 yr)	54 (30)	46 (28)	65 (30)	151 (36)	307 (36)	111 (32)
College or university	31 (17)	23 (14)	43 (20)	153 (36)	373 (43)	154 (44)
PSA, ng/ml						
Mean	12.0	11.1	NA[2]	8.3	7.7	NA[2]
Median	9.7	8.8	NA[2]	7.2	6.5	NA[2]
Range	0.1–48.0	0.1–44.0	NA[2]	0.4–60	0.4–50	NA[2]
Volume, ml						
Mean	NA[1]	NA[1]	NA[2]	43.4	40.8	NA[2]
Median	NA[1]	NA[1]	NA[2]	39.0	37.0	NA[2]
Range	NA[1]	NA[1]	NA[2]	15–206	10.0–145.0	NA[2]
Gleason score, No. (%)						
<5	56 (31)	59 (35)	NA[2]	15 (4)	40 (5)	NA[2]
6	51 (28)	37 (22)	NA[2]	150 (35)	335 (39)	NA[2]
7	31 (17)	32 (19)	NA[2]	175 (41)	384 (44)	NA[2]
8	5 (3)	6 (4)	NA[2]	18 (4)	23 (3)	NA[2]
9–10	1 (1)	0 (0)	NA[2]	22 (5)	16 (2)	NA[2]
Clinical stage, No. (%)						
T1	40 (22)	48 (29)	NA[2]	155 (37)	483 (56)	NA[2]
T2	141 (77)	118 (71)	NA[2]	122 (29)	277 (32)	NA[2]
T3	NA[3]	NA[3]	NA[2]	32 (8)	24 (3)	NA[2]

BMI = body mass index; NA = not applicable; PSA = prostate-specific antigen.
[1]Data on BMI and prostate volume not recorded according to protocol for study group 1 (Scandinavian Prostate Cancer Group Study Number 4 [SPCG-4]).
[2]PSA, prostate volume, Gleason score, or clinical stage not applicable for population control without diagnosed prostate cancer.
[3]Clinical stage T3 not eligible according to protocol for study group 1 (SPCG-4).

3. Results

3.1. Study group 1: Inguinal hernia after retropubic radical prostatectomy

The overall participation rate was 82.7%, including the population control group. Table 1 shows participation rate, demographics, age at randomization, and duration of follow-up for each group. Kaplan-Meier estimates of developing an IH after 48 mo (95% CI) was 9.3% (5.9–14.6%) in the RRP group, 2.4% (0.9–6.3%) in the WW group, and 0.9% (0.2–3.7%) in the control group. The corresponding values at the end of study were 22.0% (16.4–29.3%), 8.7% (5.2–14.3%), and 11.4% (6.1–20.9%), respectively (Fig. 1). There was a statistically significant higher occurrence of IH after surgery than in the two comparison groups. No statistically significant difference was found between the WW and the control groups (Fig. 1).

The univariable HR of developing an IH was 2.71 (95% CI, 1.47–4.99) for open prostatectomy as compared to WW (Table 2). None of the investigated potential effect-modifying/confounding factors were found to affect the risk of IH development (Table 2). In a multivariable analysis including age and previous surgery in the area, the adjusted HR for IH development was 2.76 (95% CI, 1.48–5.14) for the RRP versus WW groups (Table 3).

3.2. Study group 2: Inguinal hernia after retropubic radical prostatectomy/robot-assisted laparoscopic radical prostatectomy

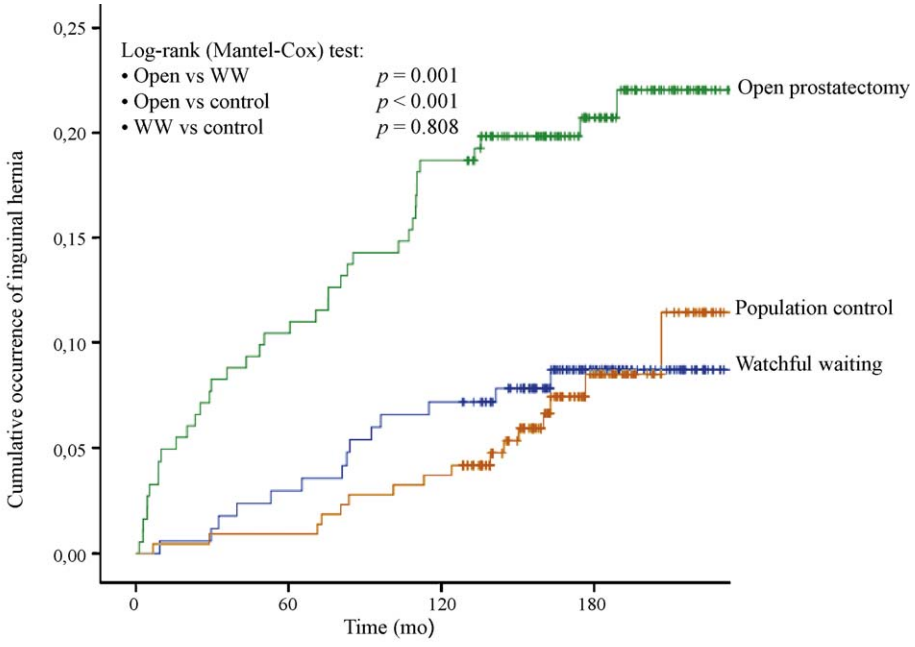
The overall participation rate was 88.4% including the population control group, Table 1 shows participation rate, demographics, age at surgery, and duration of follow-up for each group.

The Kaplan-Meier estimate of hernia at 48 mo (95% CI) was 12.2% (9.0–16.4%) in the RRP group, 5.8% (4.0–8.3%) in the RALP group, and 2.6% (1.3–5.1%) in the population control group. Only two more IHs developed after 48 mo in the control group, rendering a cumulative risk (95% CI) at the end of study of 12.2% (9.0–16.4%), 5.8% (4.0–8.3%), and 4.4% (1.8–10.7%), respectively (Fig. 2). There was a statistically significant higher occurrence of IH after RRP as compared to RALP, as well as after RRP as compared to population controls. No statistically significant difference was found between the RALP and the control groups (Fig. 2).

The univariable HR for developing an IH was 1.87 (95% CI, 1.19–2.94) for RRP as compared to RALP (Table 2). Of the investigated potential effect-modifying/confounding factors, higher tumor stage, previous surgery in lower abdominal area, and a lower BMI increased the HR for IH development (Table 2). In a multivariable analysis, including these factors and age, a known risk factor for IH development [2,16], the adjusted HR for IH development was 1.72 (95% CI, 1.04–2.86) for RRP versus RALP (Table 3).

4. Discussion

We found in the prospective randomized SPCG-4-study that IH is a postoperative complication of RRP. In a separate analysis we obtained results suggesting the incidence of IH can be reduced by using RALP. Our comparison with population controls indicates that surgically untreated PCa does not influence IH incidence.



Patients at risk

Open radical retropubic prostatectomy	181	163	148	78
Watchful waiting (WW)	166	162	155	70
Population control	213	212	206	83

Fig. 1 – Cumulative occurrence of inguinal hernia for prostate cancer patients after open radical retropubic prostatectomy or watchful waiting and for a population control without prostate cancer in study group 1 (Scandinavian Prostate Cancer Group Study Number 4) calculated from Kaplan-Meier estimate: 1 minus cumulative inguinal hernia–free survival.

Table 2 – Univariable hazard ratios for the risk of inguinal hernia development according to control variables for study group 1 (SPCG-4) and study group 2 (Karolinska)

Factor	Study group 1			Study group 2		
	HR	95% CI	*p*	HR	95% CI	*p*
Type of procedure	–	–	<0.001*	–	–	<0.001*
Robot-assisted prostatectomy	NA	NA	NA	1.0	–	–
Watchful waiting	1.0	–	–	NA	NA	NA
Open radical prostatectomy	2.706	1.466–4.994	0.001*	1.871	1.189–2.944	0.007*
Population control	0.898	0.438–1.839	0.768	0.495	0.237–1.033	0.061
Age (per year)	1.025	0.984–1.067	0.234	1.013	0.978–1.050	0.475
Age categories	–	–	0.508	–	–	0.593
<50	1.0	–	–	1.0	–	–
50–60	0.753	0.175–3.252	0.704	0.962	0.231–4.011	0.958
60–65	0.607	0.139–2.643	0.506	0.732	0.174–3.074	0.670
65–70	1.061	0.250–4.511	0.936	0.964	0.220–4.216	0.961
>70	0.930	0.200–4.313	0.926	1.383	0.294–6.524	0.682
PSA, ng/ml	1.016	0.989–1.044	0.239	1.005	0.975–1.037	0.741
PSA categories	–	–	0.708	–	–	0.959
<3	1.0	–	–	1.0	–	–
3–10	1.651	0.573–4.761	0.353	1.135	0.411–3.129	0.807
10–20	1.929	0.644–5.775	0.340	1.294	0.433–3.870	0.645
>20	1.702	0.512–5.655	0.385	1.184	0.217–6.464	0.846
Volume, ml[1]	NA[1]	NA[1]	NA[1]	1.009	0.999–1.018	0.075
Volume categories[1]	NA[1]	NA[1]	NA[1]	–	–	0.315
<25	NA[1]	NA[1]	NA[1]	1.0	–	–
25–50	NA[1]	NA[1]	NA[1]	0.979	0.505–1.897	0.950
51–75	NA[1]	NA[1]	NA[1]	1.535	0.711–3.314	0.275
>75	NAv	NA[1]	NA[1]	1.694	0.625–4.589	0.300
Gleason sum categories	–	–	0.699	–	–	0.314
<6	1.0	–	–	1.0	–	–
7	0.948	0.450–1.997	0.888	0.760	0.473–1.220	0.255
8	1.964	0.599–6.436	0.265	0.288	0.040–2.092	0.218
>9	0	0	0.979	1.392	0.549–3.530	0.486
Clinical stage categories	–	–	0.126	–	–	0.126
T1	1.0	–	–	1.0	–	–
T2	2.080	0.552–7.842	0.279	1.646	1.008–2.687	0.046*
T3	NA	NA	NA	1.003	0.307–3.279	0.995
Civic status	–	–	0.313	–	–	0.705
Married or Spouse	1.0	–	–	1.0	–	–
Living alone without partner	0.815	0.327–2.033	0.661	0.685	0.316–1.487	0.339
Living alone, occasional partner	0.391	0.095–1.601	0.191	0.806	0.326–1.994	0.641
Widower	0.348	0.109–1.113	0.075	0.538	0.075–3.868	0.538
Employment status	–	–	0.927	–	–	0.854
Employed	1.0	–	–	1.0	–	–
Old-age pensioner	1.628	0.399–6.649	0.497	0.832	0.542–1.276	0.339
Disability pension	<0.001	<0.001–5.711E229	0.969	1.065	0.330–3.429	0.917
Education	–	–	0.502	–	–	0.815
Primary school (9 yr)	1.0	–	–	1.0	–	–
Secondary school (3 yr)	0.631	0.349–1.143	0.129	1.163	0.638–2.119	0.622
College or university	0.943	0.504–1.764	0.855	0.928	0.507–1.699	0.808
Constipation, yes/no	1.764	0.750–3.053	0.247	1.426	0.872–2.332	0.158
Previous abdominal surgery, yes/no	0.949	0.820–1.099	0.487	2.362	1.547–3.605	<0.001*
Postoperative hormone treatment, yes/no	1.074	0.905–1.275	0.413	0.833	0.304–2.284	0.722
Comorbidity, yes/no	1.468	0.748–2.880	0.264	1.075	0.649–1.782	0.778
BMI, continuous[1]	NA[1]	NA[1]	NA[1]	0.855	0.791–0.925	<0.001*
BMI categories[1]				–	–	0.002*
<18.5	NA[1]	NA[1]	NA[1]	2.500	0.345–18.131	0.365
18.5–25	NA[1]	NA[1]	NA[1]	1.0	–	–
25–30	NA[1]	NA[1]	NA[1]	0.560	0.362–0.866	0.009*
>30	NA[1]	NA[1]	NA[1]	0.171	0.041–0.704	0.014*

BMI = body mass index; CI = confidence interval; HR = hazard ratio; PSA = prostate-specific antigen; SPCG-4 = Scandinavian Prostate Cancer Group Study Number 4.

*Statistically significant.

[1]Data on BMI and prostate volume not recorded according to protocol from study group 1 (SPCG-4).

Table 3 – Cox proportional hazards ratio for the risk of inguinal hernia (IH) development adjusted for known or suspected risk factors for IH development

Adjusted for:	Age		Age and BMI[1]		Age, BMI[1], and previous abdominal surgery		Age, BMI[1], previous abdominal surgery, and clinical stage[2]	
	HR	95% CI	HR	95% CI	HR	95% CI	HR	95% CI
Study group 1 (SPCG-4)								
Watchful waiting	1.0	–	NA[1]	NA[1]	1.0	–	1.0	–
Open prostatectomy	2.746	1.484–5.080	NA[1]	NA[1]	2.778[1]	1.499–5.148[1]	2.760[1]	1.481–5.142[1]
Population control	0.958	0.451–2.034	NA[1]	NA[1]	0.946[1]	0.444–2.016[1]	NA[1,2]	NA[1,2]
Study group 2 (Karolinska)								
Robot-assisted prostatectomy	1.0	–	1.0	–	1.0	–	1.0	–
Open prostatectomy	1.867	1.185–2.941	2.131	1.343–3.382	1.885	1.183–3.001	1.716	1.033–2.850
Population control	0.497	0.238–1.039	0.536	0.255–1.127	0.485	0.231–1.020	NA[2]	NA[2]

BMI = body mass index; CI = confidence interval; HR = hazard ratio; NA = not applicable; SPCG-4 = Scandinavian Prostate Cancer Group Study Number 4.
[1]Data on BMI not recorded according to protocol from study group 1 (SPCG-4); hence, adjustments not made.
[2]Clinical stage not applicable for population control without diagnosed prostate cancer.

Following the initial observation by Reagan and coworkers in 1996 [1], Lodding and coworkers published a study of 375 patients who had undergone RRP at one institution. The overall postoperative IH incidence, as judged from patient files, during a mean follow-up of 39 mo was 13.6% compared with 3.1% in a nonoperated control group. Ninety-five percent were indirect hernias; previous IH surgery, age, and stricture of the vesicourethral anastomosis increased the risk [2]. Five years later the same group published results on 664 patients who had undergone RRP. Patient-file information was combined with a patient-answered questionnaire and the cumulative postoperative IH incidence was estimated to be 19.5% after 36 mo [16]. Lepor and coworkers combined a retrospective patient-file survey and a patient-answered questionnaire and reported an incidence of 8.4% of postoperative IH among 1130 men having undergone radical prostatectomy. However, an additional 13.7% of patients had an IH repaired during the RRP [17]. In the SPCG-6, patients with locally advanced PCa were randomized to oral antiandrogen treatment daily or placebo. The occurrence of IH for men with surgically untreated PCa was 2.4% after a mean follow-up of 39 mo [18], whereas we found a Kaplan-Meier estimate of 2.4% after 48 mo of follow-up. When adding our

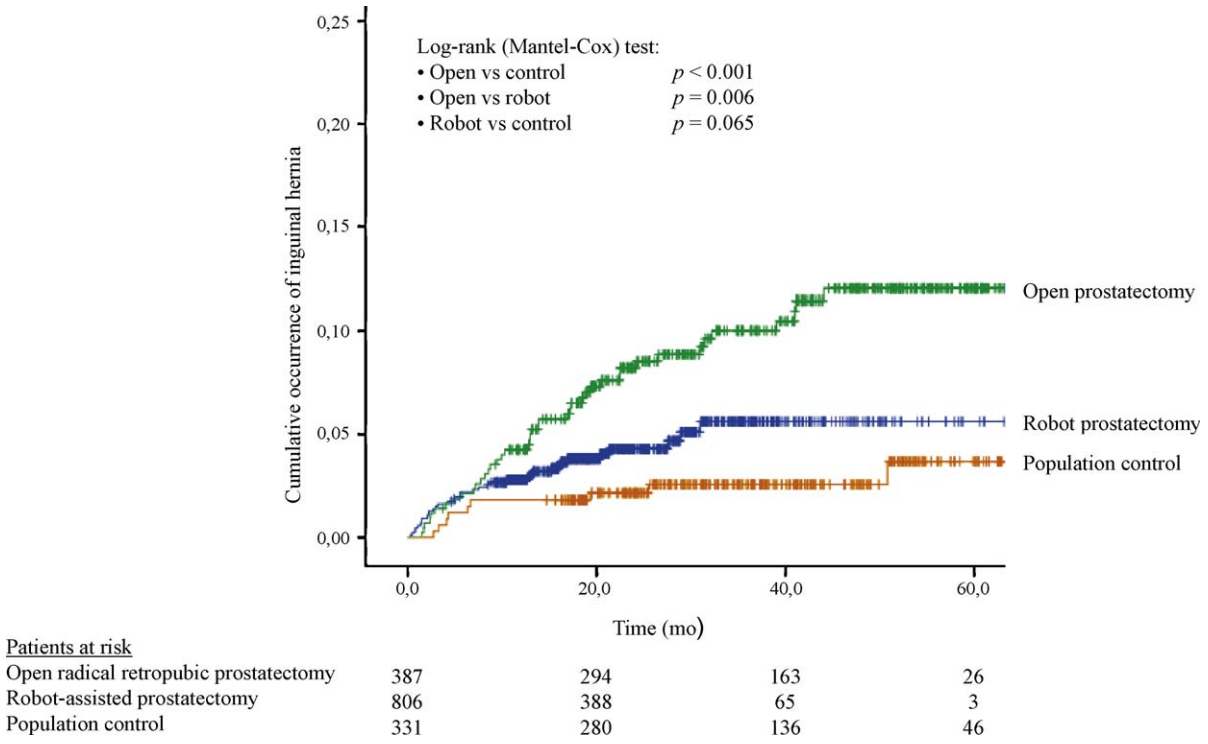


Fig. 2 – Cumulative occurrence of inguinal hernia for prostate cancer patients after open radical retropubic prostatectomy or robot-assisted radical prostatectomy and for a population control without prostate cancer in study group 2 (Karolinska), calculated from Kaplan-Meier estimate: 1 minus cumulative inguinal hernia–free survival.

prospective randomized results to these findings we believe it has been shown, beyond reasonable doubt, that IH is a complication of RRP performed through a lower midline incision.

We observed a lower incidence of postoperative IH after RALP than after RRP. The two procedures differ concerning the incision through the abdominal wall. While RRP is performed through a 10–15-cm-long incision in the midline between the symphysis pubis and the umbilicus, the RALP is performed through five or six shorter incisions spread out on the lower part of the abdomen. In a study from 2008, Koie and coworkers suggested that the length of the incision is of great importance for the development of IH. They reported a postoperative IH incidence as high as 38.7% after RRP, but only 2.9% in a group of 272 patients in whom the procedure was performed through a so called "mini-laparotomy" incision of only 6 cm [19]. Abe and coworkers obtained six IH among 43 men (14.0%, 95% CI, 5.3–28.0) who underwent laparoscopic prostatectomy and were followed for a median of 31.1 mo [5]. Matsabura and his colleagues also reported an IH incidence of 1.8% after radical perineal prostatectomy, in which the whole procedure is performed through a perineal incision and consequently there is no abdominal incision at all [20]. Sun and coworkers followed 5478 men treated by RRP for the outcome of IH repair rates. They found 17.1% at 10-yr follow-up [7]. The corresponding rate after transurethral resection of the prostate was 9.2%. Thus, the length, and possibly the placing, of the abdominal incision seems to affect the development of postoperative IH.

We used the same questions to assess occurrence of hernia in all groups, a strength indicating that measurement errors will primarily dilute the comparisons made. In the randomized study, in which we followed the intention-to-treat principle, we can expect risk factors for hernia to be equally distributed between the open-surgery group and the WW group. The nonparticipation rate is modest, lessening the likelihood of selection-induced problems. Self-assessed and self-reported IH has, in one study, shown higher sensitivity and similar specificity in detection than extraction of data from patient files [16]. However, self-reporting of IH underestimates the incidence as compared with clinical examination by a physician since subclinical IH is not reported [21–23]. In our study, no clinical examination for IH was performed, but the same degree of underreporting is likely to have occurred in all the investigated groups as the same questionnaire was used. If we had included subclinical IHs we expect the observed absolute differences between the groups would have been larger.

We lack information on presence of IH repair during RRP in group 1, but it is likely that IH repair during RRP would decrease the postoperative risk of developing an IH. No repairs were performed in group 2.

We used epidemiologic methods, as transferred to the survivorship field by the hierarchical step model [24]. In the observational setting (group 2), we do have information on several possible confounders; still, we cannot account for risk factors for hernia for which we have no information. The groups were different in several aspects. There was a tendency for higher age, educational level, BMI, preoperative PSA level, clinical stage, and previous surgery in area for the RRP patients compared with those undergoing robot-assisted surgery. The adjustments made may not fully account for the confounding factor due to measurement errors of the confounder (eg, age, BMI, and previous surgery in area). The hot-deck imputation used to generate an observational period for the controls entails an approximation; the prevalence of IH we obtained in the control population equals that of PCa patients treated without surgery in our setting and in others [24]. Generalizability to settings other than ours may be compromised by the techniques used during surgery. Nevertheless, our results do suggest a lower incidence of postoperative IH after RALP as compared to RRP.

5. Conclusions

IH causes suffering and has economic consequences for society due to sick leave and hernia-induced surgery. Patients diagnosed with PCa and their treating urologists should consider hernia as a complication when considering method of surgery. However, possibly the procedures during RRP can be modified to decrease or remove a risk of surgery-induced IH.

Author contributions: Johan Stranne 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: Stranne, Nilsson, Johansson, Wiklund, Steineck.
Acquisition of data: Nilsson, Johansson, Nyberg, Steineck.
Analysis and interpretation of data: Stranne, Nilsson, Johansson, Nyberg, Wiklund, Steineck.
Drafting of the manuscript: Stranne, Steineck.
Critical revision of the manuscript for important intellectual content: Stranne, Nilsson, Johansson, Bill-Axelson, Carlsson, Holmberg, Johansson, Nyberg, Ruutu, Wiklund, Steineck.
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