Data Extraction Form

Clinical effectiveness of robotic prostatectomy versus laparoscopic prostatectomy in the treatment of localised prostate cancer

Reviewer ID: Data extraction date:

Study ID (Author, year): Language if non-English:

Publication status: full-text papers / conference abstract / personal communication / other unpublished reports (specify)

Study IDs of any linked reports:

Study design

Aim of the study:

Study design:

☐ RCT ☐ Non-randomised comparative study ☐ Registry report

☐ Case Series ☐ Prospective ☐ Retrospective ☐ Unclear ☐ Systematic review (open prostatectomy)

For comparative studies, comparison:

☐ Robotic prostatectomy *versus* laparoscopic prostatectomy

☐ Robotic prostatectomy *versus* open prostatectomy

☐ Laparoscopic prostatectomy *versus* open prostatectomy

☐ Other comparison, specify:

For case series or registry, intervention:

☐ Robotic prostatectomy

☐ Laparoscopic prostatectomy

Number of study centres: Single centre / multicentre (specify number of centres) / not reported

Setting: hospital / other (specify) Country:

Study start – end dates: Duration of study:

For non-RCTs and case series, was patient recruitment consecutive: Yes /No / not reported

Length of follow-up:

Source of funding:

Additional information on study design:

Prospective/retrospective/not reported

For comparative studies, patients in the groups were recruited during the same period/different period/not reported

Patients				
Inclusion criteria:				
Exclusion criteria:				
Baseline Patient Characteristics				
	Intervention 1: **Robotic**	Intervention 2: **Laparoscopic**	Intervention 3: **Open**	Total
Number of patients enrolled				
Randomised (RCTs only)				
Withdrew/lost to follow-up, with reasons				
Number analysed				
Age (Mean/median, SD/range)				
BMI (Mean/median, SD/range)				
Co-morbidities, including previous abdominal or pelvic surgery, previous pelvic radiotherapy, n/N (%), specify				
Disease severity	--	--	--	--
PSA level, ng/ml, n, mean(SD) / median (range) /categorical				
Clinical stage, T1/T2/T3, specify staging method, e.g. digital rectal examination, MRI				
Biopsy Gleason Score ≤ 6, n 7, n 8-10, n				
Prostate size, ml, mean (SD) / median (range)				
Erectile dysfunction, n/N (%), specify measure and validated or not:				

Intervention

Intervention 1: **Robotic prostatectomy**

Trade name and manufacturer of robot:

☐ da Vinci system by Intuitive Surgical Inc., Sunnyvale, California, USA

☐ Other, specify: ☐ Not reported

Model number(s):

Surgical approaches:

☐ Intra-peritoneal ☐ Extra-peritoneal ☐ Not reported

Location of the operator console:

☐ In the same room ☐ An adjacent room ☐ Off-site, specify ☐ Not reported

Nerve sparing for erectile function:

☐ Unilateral, n/N ☐ Bilateral, n/N: ☐ Non- nerve sparing ☐ Not reported

Lymph node dissection:

☐ No ☐ Yes, details: ☐ Not reported

Additional information:

Intervention 2: **Laparoscopic prostatectomy**

Trade name, manufacturer, and model number of laparoscopic equipment:

Surgical approaches:

☐ Intra-peritoneal ☐ Extra-peritoneal ☐ Not reported

Nerve sparing for erectile function:

☐ Unilateral, n/N ☐ Bilateral, n/N: ☐ Non- nerve sparing ☐ Not reported

Lymph node dissection:

☐ No ☐ Yes, details: ☐ Not reported

Additional information:

Intervention 3: **Open prostatectomy**

Nerve sparing for erectile function:

☐ Unilateral, n/N ☐ Bilateral, n/N: ☐ Non- nerve sparing ☐ Not reported

Lymph node dissection:

☐ No ☐ Yes, details: ☐ Not reported

Additional information:

Safety outcomes				
Peri-operative	Timing, e.g. 6wks, 1mo, 3mo, 1 year after surgery	Intervention 1: **robotic**	Intervention 2: **laparoscopic**	Intervention 3: **open**
Equipment failure, n/N (%)				
Converted to other intervention, e.g. open operation, n/N (%), specify the route				
Blood transfusion requirement, n/N (%)	--			
Operating time, minutes, n, mean (SD) / median (range)				
Hospital stay (recovery time), days, n, mean (SD) /median (range)				
Re-admission, days, n, mean (SD) /median (range)				
Need critical care, number of patients (n/N),also number of days, mean (SD) /median (range)				
Bladder neck stenosis / anastomotic stricture, n/N (%)				
Duration of catheterisation, days, n, mean (SD) /median (range)				
Anastomotic leak, n/N (%)				
Hernia into port sites or incision sites, n/N (%)				
Infection, n/N (%), specify site				
Organ injury, e.g. bowel, blood vessels, n/N (%), specify				
Ileus, n/N (%)				
Deep vein thrombosis, n/N (%)				
Pulmonary embolism, n/N (%)				
Other peri-operative outcomes, n/N (%), specify:				
Dysfunction				
Any dysfunction including urinary, faecal, or erectile, n/N (%)				
Urinary incontinence ☐ > 1 thin pad per day, n/N (%) ☐ Other measures, e.g. subjective measure, specify				
Erectile dysfunction, ☐ International Index of Erectile Dysfunction ☐ Other measures, specify, and validated or not				
Faecal incontinence, n/N (%), specify measure and validated or not:				

Efficacy outcomes				
	Timing, e.g. 6wks, 1mo, 3mo, 1 year after surgery	Intervention 1: **robotic**	Intervention 2: **laparoscopic**	Intervention 3: **open**
Positive margin in resected specimen, n/N (%), specify definition:				
Pathology stage, pT1/pT2/pT3, specify staging method, e.g. digital rectal examination, MRI				
Pathological Gleason Score ≤ 6, n *7, n* *8-10, n*				
PSA recurrence, n/N (%), specify definition, e.g. two successive PSA levels ≥ 0.4 ng/ml):				
Local recurrence, n/N (%)				
Port site recurrence, n/N (%)				--
Metastatic disease, n/N (%)				
Required further treatment & death				
Further cancer treatment, n/N (%) in total				
Curative treatment, n/N (%)				
Resolved or died, n/N (%)				
Palliative treatment, n/N (%)				
Resolved or died, n/N (%)				
Curative and palliative treatment, n/N (%)				
Resolved or died, n/N (%)				
Treatment of urinary incontinence, n/N (%)	**			
Resolved or persistent, n/N (%)				
Treatment of faecal incontinence, n/N (%)				
Resolved or persistent, n/N (%)				
Treatment of erectile dysfunction, n/N (%)				
Resolved or persistent, n/N (%)				
Death in total, n/N (%), specify causes				
Quality of life outcomes				
Time to return to full activity, n, mean (SD) / median (range)				
Quality of life (QoL): ☐ Generic QoL, specify measure (validated) used: ☐ Disease-specific QoL, specify measure (validated) used: ☐ Other validated measures specify:				

Procedural outcomes			
	Intervention 1: **robotic**	Intervention 2: **laparoscopic**	Intervention 3: **open**
Procedures done in the centre each year, mean (SD) / median (range)			
Surgeon competence (learning curve), by surgeon and by centre	--	--	--
Number of surgeons			
Number of procedures conducted before this study			
Number of procedures conducted during this study			
Time taken to perform the procedure at the end this study, minutes, mean (SD) / median (range)			
Additional information, e.g. description about the experience of the surgeons			
Conclusion as reported by the authors of the study			
Additional information and comments			