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Functional and oncological outcomes of men under 60 years of age having endoscopic surgery for prostate cancer are optimal following intrafascial endoscopic extraperitoneal radical prostatectomy

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ABSTRACT

Background: Endoscopic extraperitoneal radical prostatectomy (EERPE) is a well-established procedure for treatment of prostate cancer (PCa). Intrafascial nerve-sparing EERPE (nsEERPE) aims to preserve the neurovascular bundle and subsequently erectile function. This study assessed the functional and oncological outcomes of nsEERPE with particular regard to younger patients.

Methods: Data on 353 men undergoing EERPE between February 2006 and December 2009 was collected prospectively. Non-nerve-sparing EERPE was performed in men diagnosed with PCa with a Gleason score >6 and/or PSA >10 $\mu\text{g/l}$. nsEERPE was undertaken in men diagnosed PCa with PSA ≤ 10 $\mu\text{g/l}$ and Gleason score ≤ 6 . Biochemical failure (BF) was defined as PSA ≥ 0.2 $\mu\text{g/l}$ after nadir or never reached nadir. Men were deemed continent if dry or using 1 confidence pad. Erections satisfactory for intercourse (ESI) or unsatisfactory for intercourse (EUI) were recorded.

Results: 102 Men (29%) had nsEERPE and 126 (36%) EERPE. pT2 positive surgical margin (PSM) rates were 20.5% for nsEERPE and 21.3% for EERPE ($P = 1$). Continence rates following nsEERPE were 59%, 86%, 97% and 52%, 76%, 86% following EERPE at 3, 6 and 12 months of follow-up respectively ($P > 0.05$). Erectile function rates for nsEERPE were 24%, 52%, 71% compared to 6%, 14%, 29% for EERPE at 3, 6 and 12 months respectively ($P < 0.001$). Erectile function in men <60 y having nsEERPE was 75% at 12 months.

Conclusions: Continence returned more rapidly and erectile function was improved following nsEERPE vs. EERPE. These results suggest that nsEERPE can be performed with particularly good oncological and functional outcome in <60 y men.

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Introduction

Endoscopic extraperitoneal radical prostatectomy (EERPE) is now a well-established laparoscopic resectional procedure for prostate cancer, with several reported advantages. Nerve-sparing intrafascial EERPE (nsEERPE) aims to preserve the periprostatic fascia (including the endopelvic fascia), the neurovascular structures within and the puboprostatic ligaments as a continuous structure.¹ As such, the cavernosal nerves are not resected potentiating the return of erectile function. Furthermore, maintenance of the puboprostatic ligaments theoretically aids rapid return of urinary continence. As increasing numbers of men are diagnosed with prostate cancer at a younger age, there is concern about over-treating these men with surgery and causing impotence and incontinence. The recent screening trials for prostate cancer have shown the potential burden of screening in that 1410 men would need to be offered screening and 48 would need to be treated to prevent one prostate cancer-related death over a 10-year period.² Conversely, previous studies have shown a benefit to surgical treatment vs active surveillance over a prolonged follow-up period, suggesting that men with a suitably long life expectancy should be treated with curative intent.³ However, if radical treatments such as surgery are to be employed in young patients with low burden prostate cancer the outcomes must be excellent. Such men have a lengthy life expectancy to suffer with impotence and incontinence. With this in mind, this study aimed to demonstrate the functional outcomes of younger men having nsEERPE and also determine if concerns over poor oncological control are valid.

Patients and methods

Between February 2006 and December 2009, 353 men had an EERPE performed by a single surgeon (SAM) who had undergone modular training in EERPE.⁴ Firstly, the surgeon developed proficiency in EERPE before developing the technically demanding skills required for the nsEERPE.

In our centre the University of Leipzig techniques of EERPE and nsEERPE have been followed as described previously.^{1,5} The nsEERPE technique leaves intact the puboprostatic ligaments, endopelvic fascia, periprostatic fascia, and neurovascular bundles (intrafascial dissection). Consecutive patients with localised prostate cancer on clinical and radiological staging (MRI and bone scan for patients with Gleason score ≥ 7 and/or PSA ≥ 10 $\mu\text{g/l}$) opting for surgical treatment were offered laparoscopic radical prostatectomy after discussion in a regional MDT and careful counselling at our institution. All of the first 100 patients were advised that nerve-sparing was unlikely to be possible, in view of the experience of the surgeon, as this is the most difficult aspect of the procedure to achieve competence in. Pelvic lymph node dissection (PLND) was performed in patients with PSA ≥ 10 $\mu\text{g/l}$ and/or Gleason score ≥ 7 . The criteria for: non-nerve-sparing EERPE were Gleason score > 6 and/or PSA > 10 $\mu\text{g/l}$; nsEERPE Gleason score of 6 and PSA < 10 $\mu\text{g/l}$ and DRE-normal. 126 Men underwent EERPE and 102 underwent nsEERPE, the remaining

125 men had an interfascial uni- or bilateral nerve-sparing procedure and were not analysed in this study. Radical prostatectomy specimens were analysed by a specialist uropathologist.

A prospectively compiled database was maintained including: patient demographic characteristics, pre-operative work-up, intraoperative details, postoperative course, pathological analysis, intraoperative and postoperative complications (classified using the modified Clavien classification⁶), follow-up for functional and oncological data. Operating time was calculated from the first skin incision to the application of dressings in theatre. Functional and oncological outcomes were estimated by incontinence rate, erectile dysfunction rate, rate of positive surgical margins (PSM) and rate of biochemical failure (BF; PSA never reached nadir (< 0.1 $\mu\text{g/l}$) or PSA ≥ 0.2 $\mu\text{g/l}$ after nadir). Follow-up included 3 monthly clinic visits in the first year, 6 monthly visits in the second year and annually visits thereafter. At each follow-up visit the PSA test result was recorded along with an assessment of functional outcomes in the database. Continence was defined as dry (completely dry or 1 pad/24 h for protection), 2–3 pads/24 h, > 3 pads/24 h and need for surgical interventions for incontinence. Potency was assessed by asking the patient if they were having erections and if this erection was satisfactory for intercourse (ESI) or unsatisfactory for intercourse (EUI). Patients were routinely commenced on a phosphodiesterase type-5 (PDE-5) inhibitor from 6 weeks post-operation, the next treatment option following PDE-5 inhibitor was the use of urethral alprostadil pellets.

All statistical analyses were performed using SPSS version 14.0 (Chicago, IL, USA). Independent samples were assessed using an independent sample t-test and rates were analysed with chi-squared test. Statistical significance was set at $P < 0.05$ level.

Results

The baseline characteristics of men undergoing EERPE and nsEERPE differed (Table 1). The median age of men undergoing nsEERPE was significantly lower, possibly due to the lower disease burden in younger men making them suitable for an intrafascial approach. As expected, the PSA and Gleason scores from prostatic biopsies were lower in men having nsEERPE reflecting our selection criteria for men having nsEERPE.

The only significant difference in intraoperative details (Table 1) was the longer operating time in men undergoing EERPE. The longer median operating time in EERPE procedures was because a PLND was performed in 106 men (84.1%), of which 7 (6.6%) were extended PLND. Additionally, the learning curve of the surgeon's initial experience with EERPE was with the non-nerve sparing EERPE.⁷

Although there were marginally more complications in the nsEERPE group, this was not statistically significant (Table 1). In the EERPE group there was a single Clavien grade 3a complication, a lymphocele which was drained percutaneously; there were no grade 3b complications. In the nsEERPE there were no grade 3a complications but two grade 3b

Table 1 – Baseline, intraoperative and postoperative outcomes for patients having EERPE or nsEERPE.

Variable	Median (range) or % variable		P
	EERPE	nsEERPE	
Number of men	126	102	–
Follow-up (months)	14 (1–37)	8 (1–24)	<0.0005
Baseline			
Age (years)	63.5 (47.8–76.5)	61.5 (44.0–72.6)	0.01
PSA ($\mu\text{g/l}$)	7.3 (2.2–31.8)	4.9 (1.7–10.8)	<0.0005
TRUS biopsy Gleason score	7 (6–9)	6 (6 only)	<0.0005
Intraoperative			
Conversions	0	0	1
Prostate weight (g)	45.0 (20.0–251.0)	45.0 (18.0–110.0)	0.3
Operation time (min)	180 (90–310)	120 (80–210)	<0.0005
Estimated blood loss (mls)	200 (0–1000)	200 (50–1000)	0.09
Postoperative			
Postoperative stay (days)	3 (1–9)	2 (1–14)	0.1
Complications, n (% of group)			
Total (% patients)	8 (6.3)	9 (8.8)	
Clavien Grade I	2 (25.0)	5 (55.6)	0.6
Clavien Grade II	5 (62.5)	2 (22.2)	
Clavien Grade IIIa	1 (12.5)	0	
Clavien Grade IIIb	0	2 (22.2)	
30 Day mortality	0	0	1

complications; namely, an anastomotic stricture requiring dilatation and a ureteric stent (used to mark the position of the ureteric orifice) which had been inadvertently sutured in place requiring cystoscopic removal.

As expected from the higher pre-operative PSA and Gleason score in men undergoing EERPE there was a significantly greater proportion of men with pT3 compared with nsEERPE (Table 2). As all men were staged as cT2 disease there was a 36.5% upstaging from cT2 to pT3 in the EERPE group with 18.6% men being upstaged in the nsEERPE group ($P = 0.007$). 34 (33.4%) of nsEERPE men were upgraded and 2 (2.0%) were downgraded; whereas, 33 (26.1%) men were upgraded and 25 (19.8%) downgraded following EERPE ($P < 0.0005$).

Overall PSM status was significantly higher in men having EERPE, this partly reflects the higher proportion of men having pT3 disease (Table 2). Importantly, there was no significant difference in the proportion of men with pT2 disease having PSMs between the 2 surgical techniques. There was a 23.1% greater rate of PSMs in pT3 disease in the EERPE vs. nsEERPE group, this was not statistically significant, possibly due to the small numbers of patients involved. The location of PSMs was similar between the 2 groups. Concordant with the PSM data, there was a significantly greater rate of BF in men having EERPE. Of the 16 men with BF following EERPE, 12 (75%) had PSMs and four men (25%) had clear margins. Neither of the two men having BF following nsEERPE had a PSM. Of the two nsEERPE patients with BF, one patient never reached PSA nadir and one patient developed BF after 5 months. Of the EERPE patients 8 men never reached nadir and of the remaining 8 men with BF the median time to BF was 18.5 months (range, 10–25 months).

Fig. 1A&B details the overall potency rates following the two procedures. With longer follow-up, potency improved in both EERPE and nsEERPE groups. As expected, there was a significantly superior erectile function following nsEERPE with 71% men having an erection (ESI or EUI) at one year compared with 29% following EERPE ($P < 0.001$, chi-squared

test). At 18 months follow-up 86.4% and 32.3% of nsEERPE and EERPE patients respectively had ESI or EUI. At 24 months 38.7% of EERPE patients had an erection, the numbers of nsEERPE patients reaching this timepoint were too small to analyse.

Fig. 2A&B outlines the continence rates for all men having nsEERPE or EERPE. There was no statistically significant difference in continence rates between men having nsEERPE and EERPE. However, there was a trend for a more rapid return

Table 2 – Oncological outcomes for patients having EERPE or nsEERPE.

Variable	EERPE	nsEERPE	P
Pathological stage, n (%)			
pT2	80 (63.5)	83 (81.4)	0.007
pT3	46 (36.5)	19 (18.6)	
Surgical specimen Gleason score, n			
2 + 3	0	1 (1.0)	<0.0005
3 + 2	0	1 (1.0)	
3 + 3	21 (16.6)	66 (64.7)	
3 + 4	82 (65.1)	32 (31.3)	
4 + 3	16 (12.7)	2 (2.0)	
5 + 3	1 (0.8)	0	
4 + 4	4 (3.2)	0	
4 + 5	2 (1.6)	0	
PSM in relation to stage, n (% per stage)			
Total	47 (37.3)	25 (24.5)	0.04
pT2	17 (21.3)	17 (20.5)	1
pT3	30 (65.2)	8 (42.1)	0.1
Location of PSM, n (%)			
Apical	27 (57.4)	13 (52.0)	0.3
Radial	12 (25.6)	8 (32.0)	
Basal	5 (10.6)	3 (12.0)	
Multiple	3 (6.4)	1 (4.0)	
BF rate in relation to stage, n (% per stage)			
Total	16 (12.7)	2 (2.0)	0.003
pT2	5 (6.3)	1 (1.2)	0.1
pT3	11 (23.9)	1 (5.3)	0.09

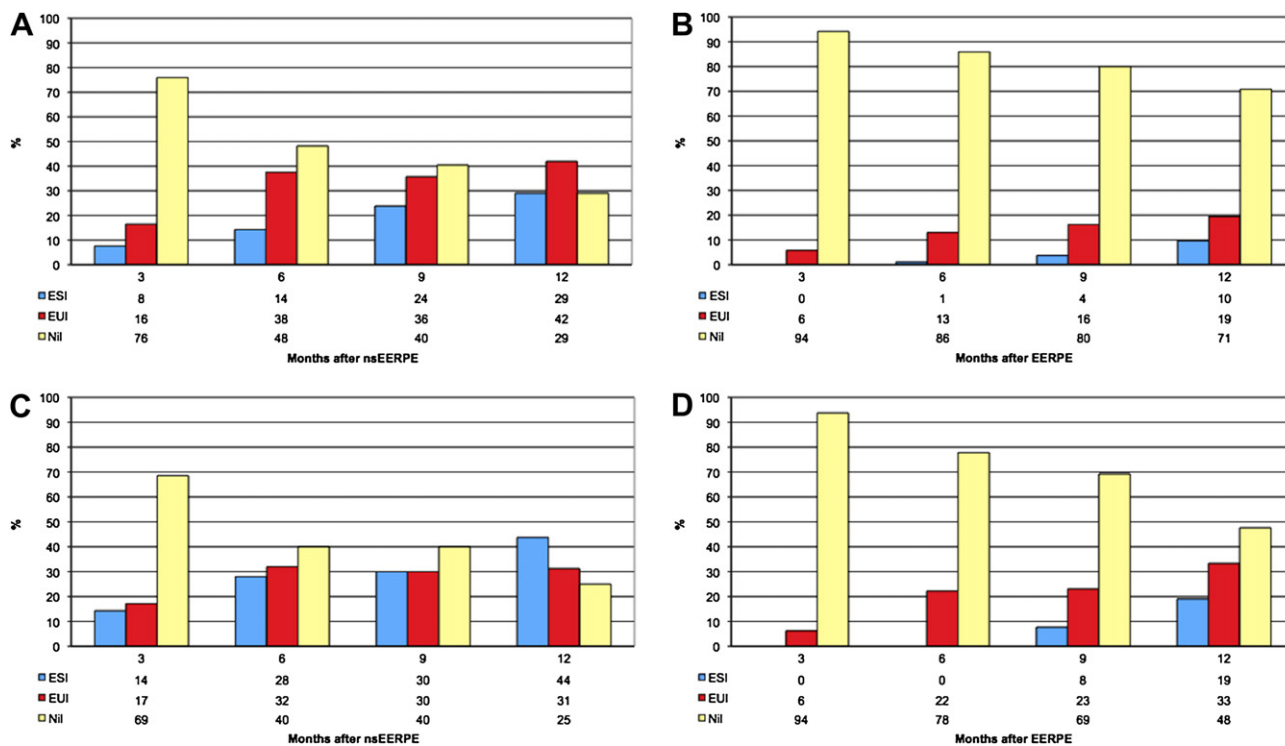


Fig. 1 – Potency rates, expressed as erections satisfactory for intercourse (ESI), erections unsatisfactory for intercourse (EUI) or nil, as a percentage of all men followed-up for: (A) all nsEERPE and (B) all EERPE; $P < 0.001$ comparing nsEERPE and EERPE at all time-points (chi-squared test). (C) nsEERPE in men < 60 years; and (D) EERPE in < 60 year men; $P < 0.03$ between nsEERPE and EERPE for men < 60 years at 3 and 6 months post operation but $P > 0.05$ at 9 and 12 months (chi-squared test). There was a significant difference in potency between men < 60 years and > 60 years having nsEERPE at 6 months ($P = 0.03$, chi-squared test) and those having EERPE at 12 months ($P = 0.02$, chi-squared test).

to full continence in the nsEERPE group. At one-year follow-up 97% men were dry following nsEERPE compared with 86% having EERPE ($P < 0.05$). Three men (2.4%) having EERPE have had an artificial urinary sphincter (AUS), whereas none of the men having an nsEERPE have had an AUS. However, by 18 and 24 months follow-up the continence of the EERPE group had not improved further.

The group of 74 men under 60 years of age were analysed separately. Overall six men (15%) and nine men (26.5%) < 60 y having nsEERPE or EERPE respectively had a PSM. For pT2 disease, four men (12%) < 60 y having nsEERPE and four men (16%) < 60 y having EERPE had PSMs. None of the < 60 y men having nsEERPE had developed BF by the time of this analysis (median follow-up 12 months). The potency rates of men < 60 y vs. men > 60 y were superior for both nsEERPE and EERPE (Fig. 1C&D), but this only reached statistical significance at 6 months for nsEERPE and 12 months for EERPE. As with the overall analysis there were significant differences in erectile function of men having nsEERPE compared with EERPE ($P < 0.03$), but only at 3 and 6 months post operation. In men < 60 y undergoing nsEERPE, in whom recovery of erectile function was particularly important, 75% men had an erection of some sort at one year and 44% were able to have penetrative intercourse. These findings marked a 30.5% absolute improvement at one-year follow-up in ESI rates compared with > 60 y men having nsEERPE, the improvement in overall erections was less impressive at 7.9%. The improvement in

erectile function for men < 60 y vs. > 60 y men having EERPE was even greater with a 32.7% improvement in overall erections at one-year post operation. The absolute improvement in ESI for the < 60 y men having EERPE compared with older patients was 13.1%. As time since surgery increases to 18 and 24 months further improvements in potency were seen. At 18 months nsEERPE patients < 60 y had erection rates of 88.9% (55.6% had ESI). At 18 months 57.1% EERPE patients < 60 y had ESI or EUI, by 24 months this figure had increased to 77.8%.

In terms of continence, men < 60 y functioned superiorly to men > 60 y. Although not reaching statistical significance, following nsEERPE the continence rate in men < 60 y was 100%, compared with 90% for EERPE patients (Fig. 2 C&D). Fewer < 60 y EERPE patients used > 3 pads than > 60 y men, as well as having a slightly superior overall continence rate; however, this was not statistically significant.

Discussion

The results of this study have confirmed the improved functional outcomes following nsEERPE compared with EERPE, especially in younger patients, but without compromise of oncological outcomes. As would be expected the potency rates following nsEERPE were significantly superior to EERPE, being highest in younger men (< 60 y) having nsEERPE. Potency rates continued to improve to 24 months follow-up and may

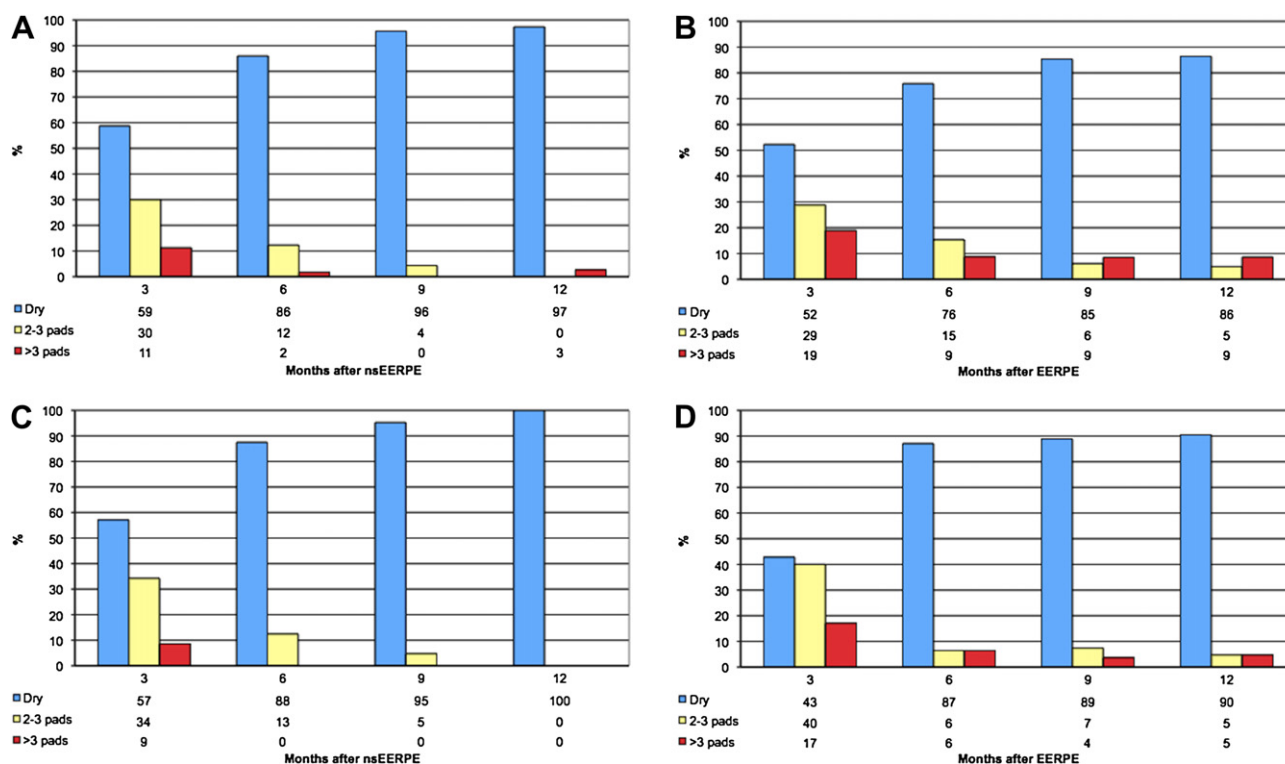


Fig. 2 – Continence rates (dry, 2–3 pads or > 3 pads) as a percentage of all men followed-up for: (A) all nsEERPE and (B) all EERPE; there was no significant difference in continence between nsEERPE and EERPE at any timepoint ($P > 0.05$, chi-squared test). (C) nsEERPE in men < 60 years; and (D) EERPE in < 60 year men; there was no significant difference in continence between nsEERPE and EERPE for men < 60 years at any timepoint ($P > 0.05$, chi-squared test). There was no significant difference in continence between men < 60 years and > 60 years having nsEERPE or EERPE ($P > 0.05$, chi-squared test).

improve beyond this timepoint. There was a trend for a more rapid return to continence following nsEERPE, in <60 y men continence reached 100% by 12 months follow-up. There was no compromise of oncological outcome, as judged by PSM and BF rates, following nsEERPE, which involves a closer dissection of the prostate. In fact, the PSM and BF rates in this series were lowest for <60 y men undergoing nsEERPE rather than EERPE. These results illustrate the low morbidity and potentially high cure rate for men <60 y having nsEERPE for treatment of low burden prostate cancer.

There are a number of strengths to this study. This study independently assessed a single experienced laparoscopic surgeon's outcomes from EERPE learnt as part of a mentored programme. A prospectively compiled database was used in this study. The outcomes presented here are from a surgeon undertaking 4–5 EERPE procedures per week. The results represent the majority of EERPEs and only nsEERPEs performed in Scotland. Thus, although the number of patients presented is smaller and follow-up is shorter than some other centres this series represents the type of experience that most surgeons in the UK would be able to accrue over the first four years of a laparoscopic prostatectomy programme. We also recognise the weaknesses of this study. There were small numbers of patients available for some of the subanalyses, meaning that statistical significance was not reached for some comparisons. The series includes the learning curve of the surgeon, non-nerve sparing EERPEs are the learning curve

cases in modular EERPE system.^{4,7} As such, the nsEERPE patients may have had superior outcomes as they were performed after the main learning curve, although this procedure has a learning curve of its own. A further limitation is the relatively short follow-up time, especially for nsEERPE, functional outcomes would be expected to improve and BF increase with longer follow-up. The functional outcomes were assessed subjectively, rather than by the use of an objective questionnaire approach (such as IIEF-5 and ICIQ-UI (short form)); note these instruments are now used in our unit, by clinical staff reviewing patients in the clinic. Finally, assessment of pre-operative potency was not complete, as such, functional outcomes may have been underestimated in this study.

Baseline and intraoperative details were comparable with benchmark figures from the University of Leipzig,⁸ where the technique used in our centre was developed. Median post-operative stay was short at 2–3 days. The rate of complications defined by the modified Calvien system was low compared with the most robust study of postoperative complications from laparoscopic prostatectomy, which quotes 14.5% medical and 24.5% surgical complications.⁹ However, there is potentially an element of underreporting of complications in the series presented here, as we did not conform to all of the 10 criteria for optimal reporting of morbidity set forth by Martin et al.¹⁰

Similar to previous studies which suggest upstaging in 24–60% men,¹¹ 35.5% of the EERPE patients in this study were

upstaged from clinically localised disease to extracapsular disease, the nsEERPE patients had a lower rate of upstaging at 18.6%. Similar to previous large series which showed 30–40% Gleason score upgrading,¹² the EERPE patients in this study had a 33.4% rate of upgrading. Thus, the rate of upgrading was slightly lower than expected in nsEERPE patients (26.1%).

The range of PSMs in the literature for contemporary radical retropubic prostatectomy series is 11–38%¹³ and 7.8–30.2% for pT2 cases.¹⁴ As such, the overall and pT2 PSM rate for the EERPE and nsEERPE procedures analysed in this study fit into the expected range. However, the EERPE PSM results are higher than in other contemporary studies on laparoscopic prostatectomy from very high volume centres.^{8,15} PSMs are an independent predictor of prostate cancer recurrence after radical prostatectomy being associated with an increased hazard of BF and local disease recurrence as well as the need for secondary cancer treatment.¹³ There is some evidence that BF is more prevalent in patients with multiple positive margins.¹³ Furthermore, after adjusting for all known adverse pathologic features, the estimated hazard ratio for progression was 2.8 (95% CI; 1.76–4.44) for posterolateral positive margins compared with 0.94 (95% CI; 0.59–1.51) for apical margins.¹⁶ It is not clear why a positive margin at one site but not another would predict for BF. Numerous theories have been suggested, including higher rates of artifactual positive margins at the apex (due to the absence of prostate capsule) and an abundance of neurovascular tissue at the posterolateral site, allowing cancer cells to migrate more easily along the nerves.¹³ Therefore, it is somewhat reassuring that the majority of the positive margins in this study were apical rather than posterolateral in nature and that there were few multiple positive margins. Finally, variations in the rates of PSMs between series can be partly explained by the different techniques of pathological analyses of the radical prostatectomy specimen and the policy of routinely obtaining intraoperative frozen sections (which has not yet been introduced at our centre).

BF is an important criteria as it precedes development of metastatic prostate cancer and prostate cancer-specific mortality by a median of 8 years and 13 years, respectively, following radical prostatectomy.¹⁷ BF occurs in 15–40% of patients within 10 years of radical prostatectomy.¹⁸ However, BF after radical prostatectomy usually occurs early. In a study by Dilliogluligil et al. 77% of BFs occurred within the first 2 years following surgery.¹⁹ As such, the BF rates accrued to date in the series presented here are satisfactory. Although, as median follow-up time lengthens these rates will increase and would be expected to stabilise as the median follow-up reaches 24–36 months. The BF rate is particularly encouraging for nsEERPE, although median follow-up is still short (8 months). Furthermore, half of the patients in the nsEERPE and EERPE group with BF never reached PSA nadir, suggesting these patients may have had micrometastatic disease at the time of surgery.

Previous studies on laparoscopic radical prostatectomy have demonstrated a range of potency of 42–76% at one-year follow-up, the range for open radical retropubic prostatectomy was 10–93%.¹⁴ However, these studies are impossible to compare head-to-head due to the heterogeneity of the definitions of potency and method of obtaining the data. The data presented here was explicitly divided into ESI and EUI.

Considering ESI and EUI rates together, EERPE patients, who were counseled not to expect any erectile function after surgery, had a 29% erection rate. In contrast the nsEERPE patients had a 71% erection rate after one year falling into the range reported previously. The potency rates (ESI) following nsEERPE did not reach the levels achieved by Stolzenburg et al. at one-year post operation of 79% (median patient age 60 y).¹ It should be noted that only 6 men in the current study used intracavernosal alprostadil injections, increased use of this medication would increase the rate of ESI in our cohort. Furthermore, there are National differences in attitudes to sex, for example senior British adults have less interest in sex than other European nations,²⁰ and as such this may influence potency rates in different series.

Further evidence for the successful adoption of the two EERPE approaches comes from continence data. Previous laparoscopic prostatectomy series have shown a continence rate of 48–91.7% at one year.¹⁴ As such, our cohort of patients has a good functional outcome from their surgery. It may be that in this initial experience of EERPE we have been concentrating on ensuring continence rather than erectile function.

In this EERPE series the trifecta of oncological outcome, potency and continence was maximised in men <60 y who had nsEERPE, as has been suggested by previous studies.¹ As such, it is becoming clear that the use of a nerve-sparing procedures, such as nsEERPE, in younger men with low volume and low risk prostate cancer treatment allows optimal oncological/functional outcomes and therefore can be considered alongside active surveillance as a treatment for low risk prostate cancer with minimised side effects. This study also adds more outcome data to the International literature on laparoscopic prostatectomy but also demonstrates real-life data from a centre providing total urology care, i.e. not only specialising in prostate cancer treatment.

Overall the results from this series are as one might expect from a department establishing a practice in EERPE. Most of the previous studies on laparoscopic prostatectomy have come from very well-established centres with a higher volume than ours. As we have shown previously the learning curve of EERPE is steep and overcome after ~50 cases.⁷ Now that the learning curve has been overcome results are expected to improve further.

Conclusion

The results from this study suggest that if prostate cancer is identified early in younger men, nsEERPE can be performed with good oncological and functional outcome. Continence returned more rapidly and erectile function was improved following nsEERPE vs. EERPE. We cannot predict which men <60 years with localised prostate cancer will develop progressive disease requiring radical therapy. However, we can advise them that functional and oncological outcomes from nsEERPE are promising.

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