Symposium

Bladder neck sparing in radical prostatectomy

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ABSTRACT

The role of a bladder neck sparing (BNS) technique in radical prostatectomy (RP) remains controversial. The potential advantages of improved functional recovery must be weighed against oncological outcomes. We performed a literature review to evaluate the current knowledge regarding oncological and functional outcomes of BNS and bladder neck reconstruction (BNr) in RP. A systematic literature review using on-line medical databases was performed. A total of 33 papers were identified evaluating the use of BNS in open, laparoscopic and robotic-assisted RP. The majority were retrospective case series, with only one prospective, randomised, blinded study identified. The majority of papers reported no significant difference in oncological outcomes using a BNS or BNr technique, regardless of the surgical technique employed. Quoted positive surgical margin rates ranged from 6% to 32%. Early urinary continence (UC) rates were ranged from 36% to 100% at 1 month, with long-term UC rate reported at 84-100% at 12 months if the bladder neck (BN) was spared. BNS has been shown to improve early return of UC and long-term UC without compromising oncological outcomes. Anastomotic stricture rate is also lower when using a BNS technique.

Key words: Bladder neck reconstruction, bladder neck sparing, lissosphincter, radical prostatectomy, rhabdosphincter

INTRODUCTION

'The three goals of radical prostatectomy (…) are cancer control, preservation of urinary control, and preservation of sexual function'.[1] As the techniques of RP have evolved, our understanding of the relevant anatomy has improved and better oncological and functional outcomes have been reported. Despite this, there remains no consensus on operative technique and there remain many technical components of the procedure itself where controversy exists. One such contentious area is the role of bladder neck sparing (BNS) versus bladder neck reconstruction (BNr) and the impact of both techniques on oncological and functional outcomes. Those in favour of BNS suggest this technique allows earlier return of continence and a lower incidence of post-operative strictures, without compromising oncological clearance.[2] Surgeons who favour BNr state concerns about compromising surgical margins with no definitive improvement in functional outcome.[3] BNS has been incorporated into open RP (ORP), laparoscopic RP (LRP) and robot-assisted laparoscopic prostatectomy (RALP) techniques. Technical aspects of BNS vary between the surgical approaches because of the technical difficulties this can present and the prolonged learning curve.[4-6] Circumferential, anterior and lateral approaches to the have all been described in ORP, LRP and RALP.[7-12]

Improved surgical techniques and appreciation of the local anatomy have seen huge modifications to the technique of RP since the first described procedure by Proust in 1901.[13] Preservation of the neurovascular bundle was first reported in 1983 by Walsh *et al.* and since then, sparing of suspensory mechanism of the urethra[11,14] preservation of urethral length[15,16] posterior rhabdosphincter sparing,[17] BNS[18] and seminal vesicle sparing[19] have all been described as important techniques for optimising functional outcome after RP. BNS has evolved from a better understanding of the anatomy and physiology of mechanisms of UC. New research based on embryological, 3D imaging and urodynamic studies have redefined our understanding of the urinary sphincter mechanism. We now understand the contributions of the BN as an integral part of larger, complex

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sphincter mechanism that consists of both striated and smooth muscle fibres,[20] rather than an independent external (rhabdo) and internal (lisso) sphincter as previously thought. The rhabdosphincter is horseshoe-shaped and overlies the circular and longitudinal smooth muscle of the urethra. During periods of increased intra-abdominal pressures it contracts and coapts the urethra.[20,21] Due to the relatively low volume of slow twitch muscle fibres compression of the rhabdosphinter cannot be sustained for longer than about 60 s.[21] During the storage phase, the lissosphincter maintains urethral resistance and is the primary mechanism responsible for maintaining resting and baseline continence. Urodynamics studies have demonstrated that an intact lissosphincter maintains continence in the absence of a viable rhabdosphincter.[20,22] BNS technique aims to leave most of the lissosphincter mechanism intact allowing preservation of its function.

We performed a search of the PubMed, Science Direct and Wiley library databases to identify original and review articles in English which addressed BNS and BN reconstruction techniques, oncological and functional outcomes of ORP, LRP and RALP, where BNS technique was used. The search terms used were BN, spare, preservation, reconstruction, urinary incontinence, positive margin, ORP, LRP and RALP. Abstracts and reports from meetings were not included. Relevant articles were reviewed, analyzed and summarized in line with the intentions of this review article. Our initial online database search returned 345 results; 133 via Science Direct, 122 via PubMed and 90 via Wiley library. We further evaluated significant articles found in the citation lists. After narrowing the search down to the relevant papers, current review included 12,806 patients in 31 original studies plus further two review articles directly pertinent to the topic of BNS and BNr. There are 19 studies describing outcomes of BNS in ORP included in the review, six studies on BNS in LRP and five original articles on outcomes of BNS in RALP. The only prospective, randomised study included patients undergoing both RALP and ORP (level of evidence 1b). Remaining studies are non-randomised prospective and retrospective studies with varying population size sample (level of evidence 2-4).

Oncological outcomes

The relationship between BNS and positive surgical margin (PSM) is well-documented in the literature [Table 1].

Table 1: Oncological outcomes of BNS

Author	Year	Sample	Study type	Technique	Total PSM	PSM BNS group	PSM non-BNS group
Gomez	1993	50	Prospective	ORP	18 (36%)	PSM at BN 6 (12%)/0 sole PSM	X
Licht	1994	206	Prospective	ORP	X	PSM at BN 6.8%	X
Wood	1995	73	Prospective	ORP	9 (12%)	PSM at BN 9 (12%) 0 sole PSM	X
Braslis	1995	134	Retrospective	ORP	7.5%	PSM at BN 7.5% 0 sole PSM	
Shelfo	1998	365	Retrospective	ORP	119 (32%)	PSM at BN 27 (7%) but 2 (0.5%) sole BN PSM	X
Soloway	2000	676					
Markowich	2000	751	Retrospective	ORP		28%	27%
Poon	2000	220	Retrospective	ORP	64 (29%)	28 out of 101 (27.7%)	36 out of 119 (30.2%)
Srougi	2001	69	Prospective	ORP	6 (10%)	4 out of 30 (13%)	2 out of 40 (5%)
Delivelotis	2002	149	Prospective	ORP	30 (20%)	PSM at BN 5 (3.3%)	PSM at BN 1 (0.7%)
Guillonneau	2003	1000	Prospective	LRP	24.9%	PSM at base 20%	X
Katz	2003	235	Prospective	LRP	62 (26%)	PSM at BN 9.75%	0
Bianco	2003	555	Prospective	ORP	178 (32%)	PSM at BN 13 (2%)/2 (0.36%) sole PSM	X
Aydin	2004	164	Retrospective	ORP	164 (100%)	PSM at BN 38 (23%)	X
Gaker	2004	355	Prospective	ORP	28 (7.8%)	0 sole PSM	X
Selli	2004	131	Retrospective	ORP	22%	5%	X
Cambio	2006	N/A	Review	ORP	X	X	X
Freire	2009	619	Prospective	RALP	12.8%	1.4%	2.2%
Chlosta	2012	194	Retrospective	LRP	14 (7%)	0 sole PSM	X
Nyarangi-Dix	2012	208	Prospective	ORP/ RALP	13.6%	14.7%, 2% sole BN PSM	12.5%
Friedlander	2012	1067	Prospective	RALP	X	109 (13.8)	38 (13.8%)

BNS=Bladder neck sparing, PSM=Positive surgical margin, BN=Bladder neck, ORP=Open radical prostatectomy, RALP=Robotic-assisted laparoscopic prostatectomy, LRP=Laparoscopic prostatectomy

However, only one study is a prospective, randomised, blinded study with a control group.[18] Gomez *et al.* in a prospective study did not find any sole PSM at BN in the cohort of 50 men undergoing ORP and BNS, although there were six patients (12%) who had multiple positive margins involving BN.[23] Wood *et al.* and Lepor *et al.* performed studies involving intraoperative biopsies of the BN after BNS.[24,25] Wood demonstrated that all nine patients (12%) who had PSM at the BN had multiple PSM's and T3 disease. This was confirmed further by Braslis *et al.,* Soloway and Neulander.[26,27] Braslis *et al.* reported there was no sole PSM at BN after ORP and 7.5% patients had PSM at the BN, which were multiple PSM's.[26] Soloway and Neulander found only 1% sole PSM at BN. In his study of 676 patients, 4.3% patients had multiple PSM also involving BN.[27] In the series of 365 patients undergoing ORP Shelfo *et al.* reported total PSM rate at 32%, but only two patients had sole BN PSM.[28] Similarly, Poon *et al.* in the retrospective cohort study of 220 men concluded no statistical difference between patients undergoing BNS versus the control group.[2] As described by Bianco *et al.* in the larger prospective studies of 555 men undergoing ORP, total PSM was 32% with 13% PSM at BN and 0.36% sole PSM at BN.[29] More recently Freire *et al.*, in a series of 619 men undergoing RALP, assessed PSM rate at the base of the prostate in the BNS versus control group.[30] Rates were 1.4% and 2.2% respectively. Similarly, Friedlander *et al.* in a retrospective evaluation of a large cohort of over 1000 men demonstrated identical PSM for BNS and control group, which was 13.8%.[31] In a new prospective, randomised, controlled and blinded study from the Heidelberg group, only 2% of BNS group had a sole PSM at the BN compared with 12.5% PSM rate in the control group.[18] Contrary to the above, Srougi *et al.* published results of their prospective study, where they ceased recruitment after 70 patients as the PSM rate was 10%, all being at the BN irrespective of the group.[3] In LRP, Katz *et al.* published results of the series, where overall PSM was 26% and PSM at BN as 9.75%.[32] During the study, they abandoned BNS approach and decreased PSM at BN to zero. Several studies stressed that appropriate patient selection is crucial in order not to compromise the surgical outcome.[12,28,33-35]

High Gleason score on the prostatic biopsies or suspicion of extra-prostatic extension increases the risk of PSM at the BN.[12,28,35] Aydin *et al.* described the significance of a sole PSM at the BN.[36] In his retrospective study of 164 men with PSM after ORP, 23% had sole PSM at the BN. Those patients had 69.8% 5-year actuarial risk of biochemical progression compared with 33% who had negative BN margin. The data highlights that the presence of a PSM at the BN has a significant impact on long-term outcomes. Both Marcovich *et al.* and Aydin *et al.* have found that a PSM at the BN results in higher rates of biochemical recurrence when compared with single or multiple PSM at other sites.[35,36] However, in 2010, Pierorazio *et al.* published the results of large review on over 17,000 patients.[37] PSM rate at the BN was only 1.2%. Patients with an isolated PSM at the BN had prostate specific antigen (PSA) free survival rate of 37% and cancer free survival of 92%, which was comparable to prognosis of patients with a seminal vesicle invasion and an extracapsular extension respectively. They concluded that American Joint Committee on Cancer should reconsider BN involvement staging as T4.

Assessing long-term oncological outcomes, we were able to identify only four studies where biochemical recurrence-free survival (BCRFS) in BNS cohorts was compared with non-BNS cohort.[16,29,31,34] Remaining data comes from prospective and retrospective single arm studies. Friedlander *et al.* assessed PSA, surgical margin status and pathological stage and grade and demonstrated no difference in BCRFS between BNS and control groups with a follow-up period of up to 72 months (hazard ratio 1.20, 95% confidence interval 0.62-2.31, $P = 0.596$). Similarly, in their prospective, controlled study, Bianco *et al.* reported that during 7-year of follow-up, BNS did not compromise disease free survival (DFS). Univariable and multivariable analyses of PSM at BNS was not a statistically important factor for DFS. Licht *et al.* also assessed DFS between BNS and non-BNS groups and showed no statistical difference. Gaker *et al.* reported that at 5.2-year follow-up, 90% of BNS group had a PSA of less than 0.2 mcg/L and 80% of the non-BNS group had a PSA of less than 0.2 mcg/L at 12.5-year of follow-up.

Functional outcomes

Urinary continence

Post-operative return to UC is similar in the reported ORP, LRP and RALP series. Where the BN was preserved UC varies between 36% and 100% at 1 month and 84% to 100% at 12 months follow-up. Table 2 summarises the relevant studies. As with the assessment of oncological outcomes, only one study provides 1b level of evidence. The remaining studies constitute level of evidence 2-4. The method of assessment of UC post-RP has always been controversial and there is no consensus definition.[38] In a prospective study Lowe defined UC as usage of zero pads per day. In his series, UC at 1 month was 23% in the BNS group and 11% in the non-BNS group were continent, which was statistically significant.[39] Long-term UC was similar, 89% and 86% BNS and non-BNS cohorts respectively. Shelfo *et al.* reported a similar rate of post-operative UC of 88% at 6 months.[28] Connolly *et al.* studied continence in patients undergoing ORP and bladder BNr (anterior bladder tube reconstruction [ABTR] vs. tennis racket repair [TRR]).[40] Pre-and post-operative urodynamics studies were performed to evaluated continence parameters. All patients were continent post-operatively at 3 months. Differences in maximal urethral closing pressures were the only statistically significant findings between both groups post-operatively. Following analysis, preservation of functional urethral length was significantly longer in patients undergoing ABTR. The authors concluded that

Table 2: Functional outcomes post-BNS

Author	Year	Sample	Study type	Technique	Continence definition	Continence rate
Gomez	1994	50	Prospective	ORP	X	100% at 6 months
Licht	1994	206	Prospective	ORP	X	36% at 1 month/77% at 3 months
Braslis	1995	134	Retrospective	ORP	0 pads	67% at 3 months
Lowe	1996	188	Prospective	ORP	0 pads	23% BNS/11% non-BNS at 1 month 89% BNS/86% non-BNS at 12 months
Shelfo	1998	365	Retrospective	ORP	Questionnaire	88% at 6 months
Poon	2000	220	Retrospective	ORP	Interview	95% BNS/96% TRR/97% ABTR at 12 months
Srougi	2001	69	Prospective	ORP	1 pad day	95% BNS/97% non-BNS at 6 months
Delivelotis	2002	149	Prospective	ORP	Interview	69% BNS/45% PLS/68% combined at 3 months 92% BNS/92% PLS/94% combined at 12 months
Gaker	2004	355	Prospective	ORP	0 pads	69% BNS/6% non-BNS at 2 weeks 78% BNS/41% non-BNS at 7 weeks
Selli	2004	131	Retrospective	ORP	1 h pad test Urodynamics	40% at 1 month 74% at 3 months
Rozet	2005	600	Prospective	LRP	ICS male	84% dry, 7% single pad for confidence at 12 months
Curto	2006	667	Prospective	LRP	ICS male	76% dry at 3 months 95% dry at 6 months
Cambio	2006	N/A	Review	ORP	N/A	N/A
Mattei	2007	100	Prospective	RALP	ICS male	92.4% dry, 5.4% 1 pad at 4 months
Freire	2009	619	Prospective	RALP	0 pads	65.6% BNS/26.5% non-BNS at 4 months 86.4% BNS/81.4% non-BNS at 12 months 100% BNS/96.1% non-BNS at 24 months
Razi	2009	103	Retrospective	ORP	Not specified	100% BNS at 32 months 88% non-BNS at 32 months
Loughlin	2010	N/A	Review	ORP/LRP/RALP	N/A	N/A
Stolzenburg	2010	240	Retrospective	LRP	ISC male	73.3% BNS/61.3% non-BNS at 3 months 86.5% BNS/80.6% non-BNS at 6 months 93.5% BNS/91.5% non-BNS at 12 months
Asimakopoulos	2010	30	Prospective	RALP	ISC male SF	80% dry at TWOC 100% dry at 1 month
Gacci	2011	2408	Prospective	ORP	0 pads	36% BNS/16% non-BNS at 1 month
Chlosta	2012	194	Retrospective	LRP	Not specified	75% at 3 months 85% at 6 months 92% at 12 months
You	2012	107	Retrospective	RALP	0 pad	62.5% BNS at 1 month 90% BNS at 3 months 92% BNS at 6 months
Grasso	2012	180	Prospective	ORP	0 pads	89% at 3 months 95% at 6 months 97.7% at 12 months
Nyarangi-Dix	2012	208	Prospective	ORP/RALP	24 h-pad-test I-QOL-questionnaire	84.2% BNS/55.3% non-BNS at 3 months 89.5% BNS/74.8% non-BNS at 6 months 94.7% BNS/81.4% non-BNS at 12 months
Friedlander	2012	1067	Prospective	RALP	EPIC	HR 1.43, 1.10-1.85, 95% CI at 5 months HR 1.29, 1.08-1.55, 95% CI at 12 months HR 1.18, 1.00-1.4, 95% CI at 24 months

BNS=Bladder neck sparing, ORP=Open radical prostatectomy, LRP=Laparoscopic radical prostatectomy, RALP=Robotic-assisted laparoscopic prostatectomy, TRR=Tennis racket repair, ABTR=Anterior bladder tube reconstruction, I-QOL=Incontinence quality of life, ICS= International Continence Society, EPIC=Extended Prostate Cancer Index, PLS=Pubo-prostatic Ligament Spare, ISC=Intermittent Self Catherisation, SF=Short Form, TWOC=Trial Without a Catheter CI=Confidence interval

preservation of urethral length may promote UC post-ORP. Furthermore, Poon *et al.* compared outcomes of BNS with ABTR and TRR.[2] At intervals of 1 week, 4 weeks, 3 months, 6 months and 12 months there was no statistical difference in UC among those groups. No significant difference in UC at 6 months was noted by Srougi *et al.*, however, due to the high prevalence of PSM at the BN recruitment to the study was halted pre-maturely.[3] A significant

improvement in UC post-BNS was reported by Gaker and Steel, and Deliveliotis *et al.*[16,41] In both prospective studies, early return of UC in BNS groups was noted compared to control groups, which was statistically important. In 2004 Selli *et al.* reported similar results from their series.[42] The study of 600 patients undergoing LRP reported a return to UC at 12 months at 84%.[43] Similar results were reported by Bordeaux[10] Leipzig[44] and Warsaw[45] groups. In our institution, we performed a retrospective analysis of 559 LRP. BNS was associated with a statistically insignificant faster recovery of UC at 3 months and statistically significant difference in UC at 12 months between BNS and non-BNS groups, 94.9% and 80.1%, respectively using one pad or less as a definition of continence. More recently, studies aiming at evaluation of BNS technique in RALP have been published. Freire *et al.* reported significantly better early UC in BNS group versus non-BNS group at 65.6% and 26.5% respectively.[30] At 2-year follow-up, there was no statistical difference between BNS and non-BNS groups and was 100% and 96.1%, respectively. In 2012 Friedlander *et al.*, in a large retrospective cohort of 1067 men showed a significant improvement in early UC between BNS and control groups particularly at 5 and 12 months follow-up.[31] In another study, You *et al.* compared functional outcomes of RALP with BNS and BNS plus posterior urethral reconstruction (PUR);[46] however, their study was performed retrospectively on a relatively small sample. Nevertheless, it demonstrated a significant improvement in return to UC between a control and PUR groups and control and BNS-PUR groups. There was no significant advantage of BNS plus PUR technique over PUR alone. The authors concluded that PUR and BNS are related with improved UC post-RALP. The only prospective, randomised, controlled, blinded study comes from the Heidelberg group.[18] They demonstrated a significant early return of UC at 4 months follow-up. 84.2% of patients with BNS were continent compared with 55.3% in non-BNS procedure. Similarly at 12 months, the difference in UC was statistically significant and rates were 94.5% and 81.4% for BNS and non-BNS groups. Moreover, in the multiple logistic regression analysis BNS was an independent positive predictor of UC.

Anastomotic strictures

Gomez *et al.* were reported that neo vesico-urethral anastomosis stricture rate were lower in BNS group compared with the non-BNS group.[23] Licht *et al.* confirmed a similar association.[34] Subsequent literature consistently supported these findings and currently there is an agreement that stricture rate post-BNS is relatively lower than in patients not undergoing BNS. Shelfo *et al* quoted 1% stricture rate in their study.[28] Poon *et al.* reported BN stricture at 5% for BNS and 11-18% for BNr techniques.[2] Gaker and Steel in 2004 reported that 2.9% of BNS patient had an anastomotic stricture.[16] Other studies present similar findings.[26,41,47] In 2004, Besarani *et al.* demonstrated that strictures occur mostly within 3 months post-surgery (75%) and are less frequent after 12 months from surgery (5%).[48] Freire *et al.* reported 1.1% anastomotic strictures in BNS compared with 0.7% in a control group.[30] More recently, the Heidelberg group did not observe the occurrence of any BN strictures post-RP in either BNS and control groups.[18]

Available evidence suggests that BNS technique is likely to be superior to non-BNS for preventing anastomotic strictures. However, most of evidence comes from non-randomised trials hence level of evidence is relatively low.

DISCUSSION

There is a growing body of literature on the role of BNS in RP, although outcome data is still mainly based on non-randomised, prospective and retrospective studies with variable sample size (level 2-4 evidence). Only one randomised, controlled, blinded study has been performed to date (level 1b). In the studies reviewed, PSM rates varied between 6% and 32%. Two series reported on the negative impact of BNS on the PSM. Katz *et al.* in his prospective series reported that after abandoning the BNS technique the PSM rate dropped by 9.75%, however, total PSM rate was still 26%.[32] Those findings were not confirmed by other studies, which documented that PSM did not negatively correlate with BNS technique. Moreover, newer, larger review postulates that sole PSM at BN is very rare (1.2%) and if present confers 12-year cancer free survival of 92%.[37] Some studies discussed the issue of indications and contra-indications for BNP technique.[12,28,33-35] While there is no agreement, it appears that the only absolute contraindication is high risk disease which increases the risk of PSM involving BN. A relative contraindication is a previous pelvic or transurethral prostate surgery as this may increase technical intraoperative difficulties. Some authors postulate additional investigations pre-operatively such as additional bladder base biopsies, pre-operative magnetic resonance imaging, and biopsies of the spared BN. The only randomised, prospective study on the subject concluded that BNS does not negatively impact oncological outcomes.[18] The sole PSM rate at BN was only 2% compared with total PSM rate being 13.6%.

This study also reported objective and subjective assessment of UC and demonstrated that BNS enables early return of UC and long-term UC. In the remaining studies included in our review, varying definitions of UC were used and therefore comparative analysis is not feasible. Two studies in the current review don't contain information on continence definition applied.[45,47]

Lowe *et al.* defined UC as zero pads per day[39] while Srougi *et al.*'s definition was 1 pad/day.[3] Other series used an open interview as a method of assessment of UC without

any validated questionnaires. More recently International Continence Society (ICS) male and ICS male short-form were utilised by others. Available data uniformly shows that UC rates post-RP with BNS are at least as good as post non-BNS and it is very likely that BNS expedites early return of UC and improves long-term UC.

CONCLUSION

With changes in surgical technique, BNS has been increasingly incorporated into the RP. Evidence summarised in this review demonstrates that BNS technique leads to early return of UC and long-term UC without compromising oncological outcomes. Anastomotic stricture rate is lower when using BNS technique. BNS is superior to non-BNS techniques and authors of this review postulate application of the method in feasible cases. High risk prostate cancer cases must be considered separately.

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