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Comparison of Health Related Quality of Life and Other Clinical Parameters between 20 g and 18 g Needles for Permanent Low-Dose-Rate Implantation in Localized Prostate Cancer

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Abstract

Introduction/objective: To evaluate short-term, treatment-specific endpoints observed following transperineal permanent prostate brachytherapy (TPPB) in patients with low and intermediate risk prostate cancer using a 20-gauge (g) needle technique as compared to traditional 18g needle technique. Our goal was to assess the impact of treatment on urinary, bowel, sexual function and bother as measured by Expanded Prostate Cancer Index Composite (EPIC) quality of life instrument prior to treatment and at 1,3,6 months after treatment. Additionally, acute urinary retention as measured by catheter use following prostate brachytherapy was investigated.

Methods and materials: This study was a single institution, balanced, randomized, non-blinded, dual arm interventional study. We accrued 242 low to intermediate risk patients between June 2010 and August 2012. There were 111 patients randomized to 18 g needles (Arm 1) and 131 patients randomized to 20g needles (Arm 2). A matched peripheral dose of 145 Gy was prescribed in all cases. Patients completed EPIC questionnaires prior to TPPB and at 1, 3 and 6 months post treatment.

Results: Upon analysis of EPIC scores at each time point post implantation, there was no significant difference between the two arms at any given time period specific to the urinary, bowel and sexual function and bother domains. However, 6/111 (5.4%) patients in Arm 1 and 0/131 (0%) patients in Arm 2 required Foley catheterization secondary to AUR, demonstrating a significant difference (p=0.007). Less than 2cc of perineal bleeding was seen in all patients, with no perineal pain or bruising reported.

Conclusion: These data demonstrate that there was no statistically significant difference regarding quality of life parameters between Arm 1 and Arm 2. There was, however, a statistically significant outcome for AUR favoring the 20 g cohort that had 0% AUR.

Keywords: Permanent prostate brachytherapy; Seed implant; Iodine-125; Quality of Life

Introduction

Due to improved treatment technique and excellent long term control rates, permanent interstitial brachytherapy for prostate cancer has gained popularity and credibility over the past decade [1-3]. Brachytherapy employing permanent placement of iodine 125 (^{125}I) seeds have reported higher cancer control rates than other treatment modalities for all prostate cancer risk groups [2-6]. Prostate seed implant related morbidity is generally low. However, with evidence of high disease control rates, emphasis is now being placed on reducing this morbidity further. The reduction in morbidity would have a valuable and important impact on patient quality of life.

Current permanent seed implantation technique for early stage prostate cancer employs standard radioactive seeds of uniform shape and size. The seeds are presented either loose or as stranded seeds within absorbable material. They are placed inside 18 gauge needles and then inserted into the prostate. A typical implant requires between 18–32 needles and 65-150 seeds. The development of thinner needles and seeds seeks to improve several treatment related side effects of permanent seed implantation.

The objective of the present study was to evaluate short-term, treatment-specific endpoints observed following transperineal permanent prostate brachytherapy (TPPB) in patients with low and intermediate risk prostate cancer. We compiled data related to ThinSeed (Oncura, a unit of GE Healthcare, Chalfont St. Giles, UK) which incorporates radioactive seeds delivered through a 20-gauge (20 g) needle technique as compared to traditional 18-gauge (18 g) needle technique. Our goal was to assess the impact of treatment with ThinSeed (Oncura) 20 g and RAPIDStrand (Oncura, a unit of GE Healthcare, Chalfont St. Giles, UK) 18 g permanent prostate brachytherapy on urinary, bowel, sexual function bother and overall treatment satisfaction domains as measured by Expanded Prostate Cancer Index Composite (EPIC) quality of life instrument prior to treatment and 1,3,6 months after treatment. Additionally, acute urinary retention as measured by catheter use following prostate brachytherapy was investigated.

Methods and Materials

This study was designed as a single institution, balanced, randomized, non-blinded, dual arm interventional study. We accrued 242 patients between June 2010 and August 2012. There were 111 patients randomized to 18 g needles using RAPIDStrand (Oncura) (Arm 1) and 131 patients randomized to 20 g needles using ThinSeed (Oncura) (Arm 2). Prior to enrollment, eligible patients were identified in accordance with the inclusion/exclusion criteria (Table1).

Inclusion	Exclusion
Prostate volume ≤ 60 cm^3	Any hormonal manipulation prior to study
Age ≥ 40 years	Any previous or planned external beam radiation, previous or concurrent cancers, distant metastases or lymph node involvement
Clinical Stage T1c-T2b Gleason ≤ 7 PSA ≤ 20 ng/ml	Any high risk prostate cancer including Gleason ≥ 8, PSA ≥ 20, Stage ≥ T3
IPS score ≤ 25	Prior TURP, hip prosthesis, psychiatric illness

Table 1: Patient Inclusion Exclusion Criteria. PSA: Prostate specific antigen, IPS: International Prostate Symptom, TURP: Transurethral resection of prostate

Patients were to be classified to have low and intermediate risk prostate cancer as defined by the following features [7]: Gleason sum 6 or less; PSA<10.1; Stage T1c-T2b or Gleason sum 6 or less; PSA greater than 10 and less than 20.1 ng/ml; Stage T2a or less or Gleason sum of 7; PSA less than 10.1 ng/ml; Stage T2b or less. Patient baseline characteristics are reported in Table 2 [8].

	18 g (mean ± SD)	20 g (mean ± SD)	p-value
Patients (n)	111	131	
PSA (ng/ml)	5.5 ± 2.4	5.3 ± 2.7	0.462
IPS	6.3 ± 5.4	6.3 ± 5.6	0.985
Volume (cm^3)	35.9 ± 14.9	35.1 ± 12.5	0.643

Table 2: Patient Characteristics with Associated P-Values. PSA: Prostate specific antigen,IPS: International Prostate Symptom,SD: Standard deviation.

Review of the tabular values (and the associated p-values), indicate that the study groups were well balanced prior to patient assessments. Table 3 displays the disease staging and Gleason Sum Score (GSS) breakdowns by needle type, additionally indicating that outcomes were not biased by discrepancy in disease severity at the outset of this clinical trial.

	18 g (median ± SD)	20 g (median ± SD)
Stage T1c	63 (88.7%)	60 (84.5%)
T2a	4 (5.6%)	7 (9.9%)
T2b	4 (5.6%)	4 (5.6%)
Gleason 3+3=6	59 (81.7%)	56 (78.9%)
3+4=7	12 (16.9%)	12 (16.9%)
4+3=7	1 (1.4%)	3 (4.2%)

Table 3: Patient Staging and Gleason by Needle Type. SD: Standard deviation.

The newer seeds of smaller diameter have the same dosimetric characteristics of standard market seeds and are supplied in an identical range of seed strengths. These characteristics allow deployment of seeds into needles of smaller gauge (20 g) than is currently used (18 g). The seeds are supplied as a string or "strand" of seeds uniformly and/or variably spaced and encased in absorbable poly glactin 910 suture. This stranded technology has been used for over 10 years. The use of smaller gauge needles is expected to reduce intra operative trauma and thus reduce or eliminate urinary obstruction, reduce or eliminate urinary bleeding, reduce or eliminate post implant erectile dysfunction and improve health related quality of life parameters as previously described.

EPIC

To minimize physician bias assessing toxicity, the patient-administered EPIC was chosen as the validated instrument to assess and quantify the results of this clinical trial.

As a validated instrument, the EPIC has been used extensively in the study and management of patients with prostate cancer [9-12]. It has proved invaluable in establishing a quantifiable record of the patient's self-evaluation of the treatment course, allowing a more detailed assessment than physician-scored instruments such as Radiation Therapy Oncology Group (RTOG) grading.

The EPIC scoring system consists of four parts: urinary, bowel, sexual, and hormonal. Each section contains a series of weighted questions to be answered by the patient. The total score for each section ranges from 0 to 100, with higher scores representing better outcomes. For example, following TPPB, the occurrence of urinary "irritations" may result in a decreased value for the urinary section score followed by an upward trend or return to at least baseline as the symptoms resolve. This analysis reports the urinary, bowel, and sexual EPIC scores following TPPB as monotherapy for treatment of prostate cancer. All statistical analysis was performed using SPSS 14.0 (IBM

SPSS, Chicago, IL). All patients signed study-specific informed consent form prior to study entry and this study was approved by IntegReview IRB on March 23, 2010 (Approval Number Thin-1).

Technique

All patients were evaluated and treated at a single institution by the same physician and support staff. Initial evaluation consisted of a history and physical, EKG, routine laboratory testing, anesthesia clearance, prostate volume study and pre-implant dosimetry planning. A matched peripheral dose of 145 Gy was prescribed in all cases.

All procedures were performed using a preplanned/preloaded needle stranded seed technique. Pre/post implant dosimetry was completed using Variseed™ (Varian Medical Systems, Inc., Palo Alto, CA) treatment planning system. Under general anesthesia, the perineum was prepared and draped in a sterile fashion. The prostate was positioned with the assistance of a biplanar transrectal ultrasound probe, a stepper stabilizer device, and perineal brachytherapy (18 g or 20 g, respectively) template. The technique for seed placement using 20 g needles was similar to that used for 18 g needles, with the only variables being the diameter of the seeds and needles (Figure 1).

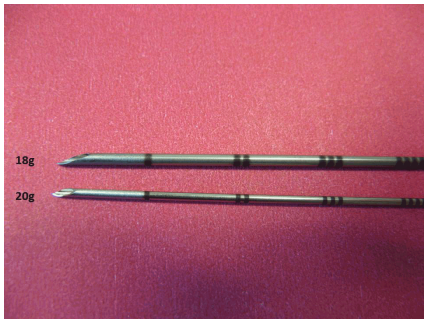

Figure 1: 20 g vs 18 g.

To address the increased flexibility of the 20 g needles, placement of the brachytherapy template directly against the perineum was critical to enhance skin penetration (Figure 2). Once skin penetration was accomplished, the needle tip was advanced to the proper z-axis depth under sagittal ultrasound imaging guidance.

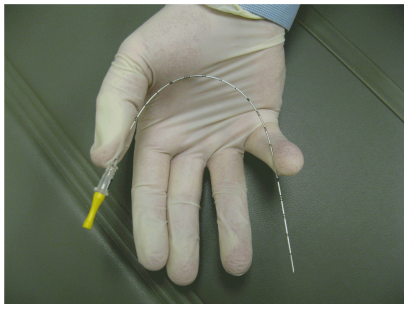

Figure 2: Needle flexibility.

Upon completion of the implant, perineal pressure was applied for 2-3 minutes to prevent hematoma. Extraprostatic seed placement was not routinely performed. No standardized extensions of prostate target volume margins were utilized, identifying the prostate and the clinical target volume as coincident. To minimize risk of rectal toxicity, no seeds were placed within the midline of the posterior prostate. Additionally, seed placement was ≥ 0.5 cm from the anterior rectal wall. Day 0 CT scan was performed one hour after implant to obtain post-implant dosimetry.

Results

Upon analysis of scores reported for each sub-section of the EPIC questionnaire at each time point post implantation, there was no significant difference between the two arms at any given time period specific to the urinary, bowel and sexual function and bother domains (Table 4).

	ARM 1 18 g needle/ RapidStrand (mean ± SD)	ARM 2 20g needle/ ThinStrand (mean ± SD)	P value
Pre-implant EPIC Urinary	91.1 ± 9.5	91.0 ± 10.1	0.91
Pre-implant EPIC Bowel	94.7 ± 7.7	94.5 ± 7.3	0.881
Pre-implant EPIC Sexual	59.9 ± 24.6	57.9 ± 25.2	0.563
1 month EPIC Urinary	69.1 ± 18.0	71.3 ± 18.4	0.405
1 month EPIC Bowel	94.7 ± 7.7	94.5 ± 7.3	0.881
1 month EPIC Sexual	59.9 ± 24.6	57.9 ± 25.2	0.563
3 month EPIC Urinary	77.9 ± 16.2	77.0 ± 14.7	0.714
3 month EPIC Bowel	94.7 ± 7.7	94.5 ± 7.3	0.881
3 month EPIC Sexual	59.9 ± 24.6	57.9 ± 25.2	0.563
6 month EPIC Urinary	82.9 ± 13.4	82.7 ± 14.1	0.911
6 month EPIC Bowel	90.7 ± 10.9	89.3 ± 14.4	0.485
6 month EPIC Sexual	51.8 ± 25.4	49.8 ± 25.4	0.612

Table 4: EPIC scores. EPIC: Expanded Prostate cancer Index Composite, SD: Standard deviation.

However, 6/111 (5.4%) patients in Arm 1 and 0/131 (0%) patients in Arm 2 required Foley catheterization secondary to AUR, demonstrating a significant difference (p=0.007). No perineal pain or bruising was reported. Blood loss was minimal in all patients; staff noted visually, perineal spotting was minimal with 20 g as compared to 18 g (Figure 3). Despite the difference regarding needle flexibility, requiring minor modifications in technique, implant time was similar to that of our experience with 18g needles, with median implant time of 17 minutes (range, 8-32 minutes).

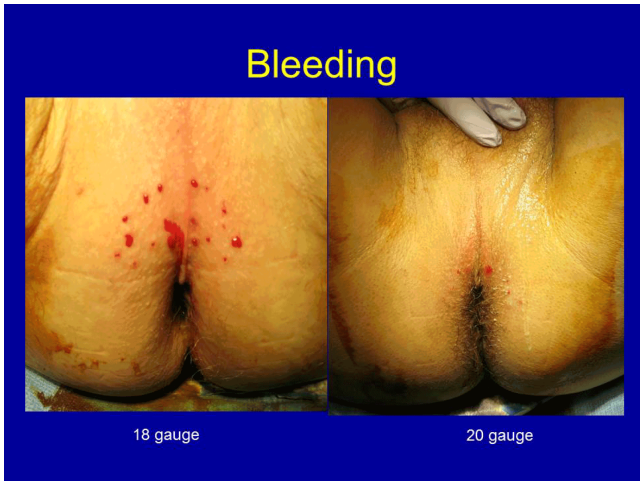

Figure 3: Perineal spotting.

Discussion

Edema of the prostate due to needle trauma or radiation causes some degree of urinary obstructive symptoms in all patients postoperatively. This gradually resolves within [6-12] months [13]. Because some patients with high IPS scores and multiple risk factors have higher risk of post implant obstruction, it has been suggested that other therapies should be considered in these patients [14]. Acute urinary retention (AUR), defined as the immediate requirement for catheterization, is typically seen within 1 week of the procedure and reported incidence ranges are between 0-34% [13-19].

AUR, when it occurs, has a mean duration of 21 days, with a range of one day to twenty-six weeks [14,17]. Acute post implant obstruction is believed to be due to the traumatic effect on the prostate and urethra from the implant needles rather than a dose effect of the seeds, especially for I-125, with a 60 day half-life [14,17,20].

More needles are used for large glands, and with that, there is the possibility of more trauma to the prostate. Lee et al associated higher number of needles with a greater risk of AUR [21]. However, Bucci et al. noted that the number of needles did not independently correlate with AUR [14]. These data suggest that trauma to the prostate can also be caused by multiple needles sticks and not just the total number of needles. Eapen et al. demonstrated that needle trauma around the urethra due to the number of needle sticks was a significant factor in AUR [20]. Keyes et al noted that the number of needles contributes to AUR but that, over time with more experience, AUR decreased from 17% to 6.3% [22].

Edema, as measured by the ratio of the CT scan prostate volume post implant to the pretreatment ultrasound treatment volume, also was predictive of AUR [22]. Buskirk et al. demonstrated on transperineal template guided prostate biopsies that the number of cores taken correlated with AUR in the absence of seed deposition [23]. This strongly suggests that trauma plays a significant role in the etiology of AUR, and that reducing edema would be valuable. Additional reported factors to the development of AUR are increasing prostate size13, [24,25], high dose to the urethra [26], higher initial IPS scores [14-15], low urinary flow rates [27], use of hormonal therapy [15] and diabetes [14].

Attempts to decrease AUR from edema due to needle trauma or radiation effect associated with seed implantation have been made employing steroids or non-steroidal inflammatory drugs. Merrick et al. observed markedly decreased prostate volumes when peri-operative steroids were administered based on postoperative day 3 imaging. Many of these patients, however, experienced edema once again by the second week after the implant [28]. Feigenberg et al. found a significant decrease in the need to use a catheter with the use of peri-operative treatment with Celecoxib [17]. The routine use of Alpha blockers did not seem to reduce the risk of acute urinary retention [29]. Additional measures, such as increasing seed strength to reduce the number of required needles have also been employed [22]. This particular technique is concerning as it potentially increases the risk for complications and treatment failure.

CT-MRI fusion study evaluated by the Tausky et al demonstrated that post implant edema is greatest at day 0 (31% larger prostate) and decreases to approximately 5% by day 30 [30]. The amount of edema correlated with the number of needles and prostate size. Of note, small glands proportionately swelled greater than large glands.

Implant quality is traditionally defined by the percentage of prostate receiving 100% (V100) of the minimum prescribed dose. The dose delivered is determined by performing a prostate CT immediately or several weeks after the implant and then calculating the dose to the gland [31]. Wehle et al. have demonstrated that due to prostate edema, there can be a significant change in calculated dose coverage (V100) from day 0 to day14 and day 28 dosimetry [27].

The major problem of swelling, beyond increasing the risk of AUR, is the problem of accurately defining the prostate volume on post implant CT scans. Swelling can make it difficult to delineate the prostate on CT from surrounding tissue. Some centers have used MRI imaging to define the contour of the gland; however, the MRI cannot accurately image the individual seeds. The MRI must be fused with the CT images to obtain an accurate portrait of the dosimetry. The cost in time and expense precludes this methodology from use in standard practice. It is hoped that by reducing the swelling associated with the implant, the accuracy of post-operative prostate contouring using traditional CT approaches will improve. A recent study by Sylvester et al demonstrated that ThinStrand implants resulted in markedly improved dosimetric parameters when compared to 18 g [32].

Consistent dose distribution may be an important factor in tumor control and patient morbidity. Patients undergoing implantation are subject to the effects of dose distribution for many months after the implant. Changes in prostate size and shape can affect dose distribution, particularly to the urethra. While the duration and severity of these effects can be influenced by pretreatment co morbidities i.e. medications, androgen deprivation therapy (ADT), prostate volume and prostate size, the dose to the urethra may be a significant factor in predicting long term morbidity such as incontinence and urethral strictures [18,33]. In the first month, prostate edema may significantly change the size of the prostate. It would appear reasonable that reducing edema by causing less trauma would also improve dose distribution throughout the gland.

Critical to a successful implant is the accurate execution of the preoperative plan. Needle insertions during the implant can cause the prostate rotation [24]. Sharper needles lessened this tendency, and it is anticipated that a further reduction in needle diameter will reduce this

prostate movement. The etiology of erectile dysfunction after seed implantation is multi factorial and likely related to both the trauma of the procedure and the effect of radiation on the nerves and vessels responsible for erectile physiology [34]. These vessels and nerves are closely adjacent to the prostate and therefore subject to the trauma of the needles. Evidence of a possible trauma related effect due to needle insertion is the observation of immediate loss of erectile ability after the implant. It was anticipated that a smaller diameter needle would result in less trauma and therefore less erectile dysfunction. As the dose to the nerve is similar to standard technique, it was not expected that this technique would alter the effect of radiation induced erectile dysfunction.

Conclusion

These data demonstrate that there was no statistically significant difference regarding quality of life parameters between Arm 1 and Arm 2. There was, however, a statistically significant outcome for AUR favoring the 20 g cohort that has 0% AUR. In the future, we plan to analyze the dosimetric values for these two study groups to ascertain if there is less edema in the 20 g needle group that would conceivably result in greater post implant dosimetric values.

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