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Celebrating Research, Accomplishments (Creative) *and* Scholarship
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Daily patient setup error in prostate image guided radiation therapy with fiducial-based kilovoltage onboard imaging and conebeam computed tomography

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Background: This study examined the interfraction setup error in patients undergoing prostate radiotherapy using fiducial markers and on-board imaging.

Methods: Patients (n=53) were aligned to the treatment isocenter by laser followed by orthogonal kilovoltage (kV) radiographs to visualize bony anatomy and implanted fiducial markers. The magnitude and direction of couch shifts for isocenter correction required was determined by image registration for bony anatomy and fiducial markers. Twice weekly, 25 of the 53 patients also underwent conebeam computed tomography (CBCT) to measure any residual error in patient positioning. Based on individual coordinate shifts from CBCT, a net three-dimensional (3D) residual shift magnitude vector R was calculated.

Results: The average couch shifts were 0.26 and 0.40 cm in inferior direction and 0.25 and 0.33 cm in superior direction for alignments made with bony anatomy and fiducial markers, respectively ($P < 0.0001$). There were no significant differences noted in the vertical or lateral planes between the two image registration methods. In subset of 25 patients, no residual shift from fiducial plain film set up was required with CBCT matching in 66.5%, 52.4% and 57.9% of fractions for longitudinal, vertical and lateral planes, respectively, with majority (79%) of patients having a net residual 3D shifts of < 0.3 cm. The use of CBCT increased average treatment time by approximately 6 min compared to kV radiographs alone.

Conclusions: The residual setup errors following daily kV image guided localization, as determined by CBCT, were small, which demonstrates high accuracy of kV localization when fiducial markers are present.

Keywords: Conebeam computed tomography (CBCT); fiducial markers; image guided radiation therapy (IGRT); prostate cancer

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Introduction

Since the field's inception over a century ago, radiation oncology has been faced with the fundamental challenge of delivering radiotherapy to malignant tissue while sparing surrounding healthy organs. In order to address this issue, researchers have delved into image-guided radiation therapy (IGRT), which refers to the integration of radiation planning, patient positioning, and treatment delivery with

new and emerging image-based tumor definition methods (1). While advances in tumor volume delineation and the practice of IGRT have led to more precise treatments, the need for increased accuracy in beam targeting remains (2). Greater accuracy would allow conforming of the planning target volume (PTV) more closely to the clinical target volume (CTV), which would reduce the volume of healthy tissue irradiated. In turn, this could allow radiation dose escalation resulting in better local control with decreased

associated morbidity. The benefit of dose escalation with conformal radiation delivery has already been well-demonstrated in the treatment of prostate cancer (3).

One of the commonly practiced method for verifying interfraction changes involves the comparison of megavoltage (MV) X-ray portal images to the reference kilovoltage (kV) X-ray images obtained during computed tomography (CT) simulations or to digitally reconstructed radiographs (DRRs) (4). To circumvent the poorer resolution of MV imaging, a number of studies have been conducted implementing planar and volumetric kV imaging (5,6). The On-Board Imager™ (OBI) has been commonly used to provide this type of imaging. It consists of a diagnostic X-ray tube and kV flat-panel imager mounted on the treatment machine gantry via robotic arms that operate along three axes of motion. In recent years, the OBI has been used to verify patient positioning via two dimensions—planar orthogonal kV radiographs, and via three dimensions—kV conebeam CT (CBCT).

kV CBCT allows for the reconstruction of a three-dimensional (3D) CT image from data collected during a single gantry rotation around a stationary patient (7). Such an imaging system has been shown to be capable of producing soft tissue images with excellent spatial resolution in a seamless, efficient manner (8). Thus, it has often been used preferentially over paired orthogonal kV images in cases where 3D soft tissue detail is important for patient position verification (5). It has also been used when treating small targets without fiducial markers, when using a small number of treatment fractions, and when performing adaptive radiotherapy (5). Still, while kV CBCT provides better soft tissue contrast, its use could be limited by the increase in radiation session length it requires as well as the greater dose it delivers to the patient in comparison to planar imaging (9).

In cases of prostate cancer, both of these image registration methods have provided daily image guidance in an attempt to more accurately deliver radiation (4,6). The location and mobility of the prostate makes its accurate localization using external markers such as skin tattoos and bony anatomy difficult. While ultrasound has also been widely utilized for localization of the prostate, it was found to be less accurate than kV imaging with fiducial markers (10). Fiducials—radioopaque typically gold, cylindrical seeds—are implanted into the prostate via needle under transrectal ultrasound guidance (11). Imaging techniques using fiducials located within the prostate allows for more accurate targeting of the mobile organ and reduces interfractional variation

of radiation. Greer *et al.* reported offline bony anatomy systematic errors of 1.6, 2.5 and 4.4 mm in the right-left (RL), superior-inferior (SI), and anterior-posterior (AP) directions, respectively (12). McNair *et al.* reported offline bony anatomy systemic errors of 1.3, 1.9, and 2.5 mm and online fiducial systemic errors of 0.9, 1.1, and 1.0 mm in the RL, SI, and AP directions, respectively (13). Both studies also calculated the margins to account for set-up error for each technique which was of 6, 9, and 13 mm (12) and 4.7, 6.3, and 8.4 mm (13) in the RL, SI, and AP directions with bony anatomy and 2, 4, and 5 mm (12) and 1.3, 1.2, and 1.2 mm (13) in these directions with online fiducial markers.

Because of the accuracy of kV planar imaging with fiducials, the necessity for CBCT has been questioned (12,13). The purpose of this study was to compare interfraction patient setup error in prostate radiotherapy using planar kV radiographs with patient anatomy, planar kV radiographs with fiducial markers, and CBCT with fiducial markers. With this frame of reference, the utility of CBCT was also assessed.

Materials and methods

Simulation

A total of 53 patients with prostate cancer undergoing radiation therapy were included in this study. All of the patients had three radioopaque fiducial markers implanted in their prostate 1–2 weeks prior to their treatment planning session, allowing for post-implantation seed migration. At the time of simulation, no special bowel preparation was performed and patients were instructed to have an empty bladder for both simulation and treatment. Patients were instructed to remove all clothing from the waist down to minimize displacement from the garments.

Immobilization and alignment consisted of supine positioning, indexed F roll under the head, hands folded on chest, and a leg-immobilization device encompassing the foot and separating the legs. Patients were straightened visually using the sagittal laser and prepared for scanning. A CT scan was performed using a Phillips Brilliance Big Bore scanner employing the pelvis protocol. Orthogonal scout films were obtained to check for pelvic rotation and tilt and patients were aligned accordingly. Patient were scanned from L1 vertebral body to below the lesser trochanter using 3 mm slices assuring all three fiducials were visible. Anterior, right and left lateral tattoos were placed at the isocenter coordinates. Following CT simulation and

treatment planning, all patients were treated on a Varian iX® or Trilogy® linear accelerator equipped with on-board kV imaging capabilities.

Positioning and OBI

On days of treatment, patients were placed in the same position as the simulation and aligned to their three skin tattoos using treatment room sagittal and transverse lasers. An OBI (Varian Medical Systems) was utilized to take an orthogonal film pair. Visual confirmation of matching bony anatomy was performed to identify potential patient rotation, and, if discovered, the patient was realigned and re-imaged. Patient rotation was checked on the initial OBI films by examining the pelvic brim and obturator foramen for rotational displacement. If discovered, the patient was asked to raise and lower their pelvis and visually examined for rotation and straightness and setup again to tattoos and coordinates. This practice took care of all rotational misalignments we experienced.

During this process, implanted fiducial markers were also contoured on the anterior and lateral projections of the DRRs, and the kV images were overlaid onto them using the Varian® OBI matching program then manipulated in the inferior-superior, AP and left-right directions. Both automatic and manual matching was employed and implanted seeds were moved to the center of the DRR contour. If all three contours were misaligned, the patient would be repositioned and reimaged. When fiducials were matched, corresponding shifts were also sent electronically to the linear accelerator and the treatment table was moved to the desired location. All OBI film movements were reviewed and approved by the physician post treatment, or, pre-treatment if there was any question regarding patient or fiducial positioning.

Conebeam CT image acquisition

Twenty-five of the 53 patients in this study also underwent CBCT guided positioning in addition to orthogonal films. Twice a week, a 360° CBCT was performed immediately after fiducial matching shifts were carried out with the Varian kV OBI system, version 9. Scans were acquired using the pelvis protocol, 512 by 512 pixels and half-bowtie fan mount. After acquisition and reconstruction, the CBCT was matched in the transverse, sagittal and coronal planes to the fiducials in the original CT simulation scan and residual movements were performed and recorded for study

purposes. All CBCT scans were reviewed and approved by the physician post treatment.

Treatment

Treatment was delivered by a Varian iX® or Trilogy® linear accelerator using 6 MV photons as prescribed in an intensity modulated radiation therapy treatment plan produced using Phillips Medical Systems, Pinnacle 3 (version 8.0 m) treatment planning system. Fractionation of 44 treatments to a total dose of 7,920 cGy was administered daily.

Statistical analysis

Descriptive statistics were calculated for shifts recorded using planar kV radiographs with bony anatomy and fiducial markers for all 53 prostate cancer patients. The Chi-square test was used to compare frequencies of shifts in longitudinal (SI), vertical (AP) and lateral (RL) planes. A "No shift" was defined as required movement of less than 1 mm (<0.1 cm). The difference in mean shifts in each direction was compared using a repeated measures ANOVA analysis using Proc MIXED in SAS 9.1 system (SAS Institute, Cary, NC, USA). The analysis allows modeling of variance-covariance matrix among repeated shifts recorded for each patient over the course of radiation treatment period.

In a subset of 25 patients who also underwent CBCT guided positioning residual set-up shifts were recorded and descriptive statistics and frequencies were calculated for each direction. Based on individual coordinate shifts, a net 3D residual shift magnitude vector "*R*" was calculated for each fraction according to following equation:

$$R = \sqrt{(X)^2 + (Y)^2 + (Z)^2}$$

where *R* is the net residual 3D shift while *X*, *Y* and *Z* are residual shifts recorded in left-right, inferior-superior and AP directions, respectively. The frequencies of occurrence of residual 3D shifts were calculated for the CBCT subset. We regarded the residual 3D shift magnitude *R* as a useful figure of merit when considering the difference between planar imaging and CBCT for patient alignment. This is because PTV margins in conformal radiotherapy are generated in a 3D manner; therefore any discussion of the adequacy of setup precision is best framed in 3D terms as well. In addition, basing the analysis on the residual 3D shift *R* leads to an essential finding that is more compact and more easily communicated than is possible when

Table 1 Comparison of mean shifts (cm) recorded with kV radiographs using bony anatomy and fiducial markers among 53 prostate cancer patients

Shift direction	Bony anatomy				Fiducial markers				P value
	n	Mean	SE	Range	n	Mean	SE	Range	
Longitudinal									
Inferior	1,323	0.26	0.02	0.10-1.6	1,425	0.40	0.02	0.10-2.2	<0.0001
Superior	691	0.25	0.04	0.10-3.0	682	0.33	0.04	0.10-2.4	<0.0001
Vertical									
Anterior	965	0.38	0.02	0.10-2.2	1,000	0.37	0.02	0.10-1.6	0.333
Posterior	1,133	0.37	0.02	0.10-2.1	1,118	0.36	0.02	0.10-2.1	0.322
Lateral									
Left	1,091	0.46	0.02	0.10-2.2	1,107	0.46	0.02	0.10-2.2	0.845
Right	1,069	0.46	0.02	0.10-2.2	1,047	0.46	0.02	0.10-2.4	0.721

kV, kilovoltage; n, number of directional shifts; SE, standard error.

each coordinate axis is examined separately. A two-sided hypothesis was used for all tests, and a probability value of less than 0.05 was considered statistically significant.

Results

Fifty-three patients underwent a total of 2,334 radiation treatment fractions. The mean shifts made by alignment with fiducial markers were significantly greater in the inferior and superior directions compared to alignment with bony anatomy alone (0.40 *vs.* 0.26 cm and 0.33 *vs.* 0.25 cm with $P < 0.0001$, respectively). There were no statistically significant differences in mean shifts between bony anatomy and fiducial markers in different directions of vertical or lateral planes. A comparison of mean couch shifts (cm) recorded with kV radiographs using bony anatomy and fiducial markers is presented in *Table 1*.

Bony anatomy *vs.* fiducials on kV images

Table 2 presents a comparison of the frequency with which couch shifts were required in those 53 patients following alignment to bony anatomy *vs.* fiducial markers. There was a significantly greater frequency of shifts in the inferior direction using fiducial markers compared to bony anatomy (61.1% *vs.* 56.7%, $P < 0.002$). In addition, alignment to bony anatomy in the longitudinal plane more often resulted in no shift following initial patient setup when compared to fiducial marker alignment (13.7% *vs.* 9.7%, $P < 0.0001$). There were no statistically significant differences in

frequencies of shifts made in the vertical or lateral planes between these two image registration methods.

kV image *vs.* CBCT

In the subset of 25 patients (with 439 treatment fractions), once patient alignment and shifts were completed using kV images to fiducial markers, CBCT was done to match the fiducial markers to assess the need for any additional shifts. The residual shifts were recorded between the kV image-guided fiducial alignment and CBCT-guided fiducial alignment in *Table 3*. No residual shift was recorded in 66.5%, 52.4% and 57.9% of fractions for longitudinal, vertical and lateral planes, respectively. The mean residual shift was 0.17, 0.17, 0.16, 0.21, 0.15 and 0.15 cm in inferior, superior, anterior, posterior, left and right direction respectively. For net residual 3D shift *R*, the percentage of total treatment fractions requiring no shift, 0.1-0.3 cm shift, 0.3-0.5 cm shift, 0.5-0.7 cm shift, and greater than a 0.7 cm shift are presented in *Figure 1*. The majority (79%) of treatments required less than a 0.3 cm shifts or no shift using CBCT imaging after pre-alignment based on fiducials using kV imaging.

Treatment time

An analysis of randomly selected one-third of the study participants who received CBCTs along with OBI and their treatment, revealed patients having a CBCT were on the table about 14 min, whereas non-CBCT treatments were slightly over 8 min, which includes OBI seed matching. The

Table 2 Comparison of frequency of shifts recorded with kV radiographs using bony anatomy and fiducial markers among 53 prostate cancer patients

Shift direction	Bony anatomy (N=2,334), n (%)	Fiducial markers (N=2,334), n (%)	P value
Longitudinal			
No shift	320 (13.7)	227 (9.7)	<0.0001
Inferior	1,323 (56.7)	1,425 (61.1)	0.002
Superior	691 (29.6)	682 (29.2)	0.773
Vertical			
No shift	236 (10.1)	216 (9.3)	0.322
Anterior	965 (41.4)	1,000 (42.8)	0.300
Posterior	1,133 (48.5)	1,118 (50.0)	0.310
Lateral			
No shift	174 (7.5)	180 (7.7)	0.740
Left	1,091 (46.7)	1,107 (47.4)	0.639
Right	1,069 (45.8)	1,047 (44.9)	0.518

"No shift" defined as less than 1 mm (<0.1 cm) shift. kV, kilovoltage; N, total shifts; n, number of directional shifts.

Table 3 Descriptive statistics for residual shifts (cm) recorded with CBCT over fiducial marker position among 25 prostate cancer patients with 439 treatment fractions

Shift direction	n (column %)*	Mean	SE	Median	Range
Longitudinal					
Inferior	69 (15.7)	0.17	0.01	0.10	0.10-0.70
Superior	78 (17.8)	0.17	0.01	0.10	0.10-0.70
No shift	292 (66.5)		Not applicable		
Vertical					
Anterior	27 (6.2)	0.16	0.01	0.10	0.10-0.40
Posterior	182 (41.5)	0.21	0.01	0.20	0.10-0.80
No shift	230 (52.4)		Not applicable		
Lateral					
Left	69 (15.7)	0.15	0.01	0.10	0.10-0.40
Right	116 (26.4)	0.15	0.01	0.10	0.10-0.60
No shift	254 (57.9)		Not applicable		

*, Number and percentage of subjects with directional or no shift (<1 mm) out of 439 total treatment fractions. CBCT, conebeam computed tomography; SE, standard error.

difference was statistically significant ($P < 0.05$) using *t*-test. These calculations were retrospectively performed using the documented beginning of the OBI film session and the time the last field was treated.

Discussion

Similar to the studies by Greer *et al.* and McNair *et al.*, our data also suggest that kV imaging with alignment to fiducial

markers is superior to alignment using bony anatomy alone (12,13). Mean shifts in the inferior and superior directions were significantly greater, whereas AP and left-right shifts did not differ. The larger daily shifts with fiducial markers are reflective of the fact that prostate is an internal organ that can move with respect to the skin markings and bony anatomy, requiring more shifts to account for the location variability. The reason for greater shifts required in the inferior-superior direction is unclear but review of

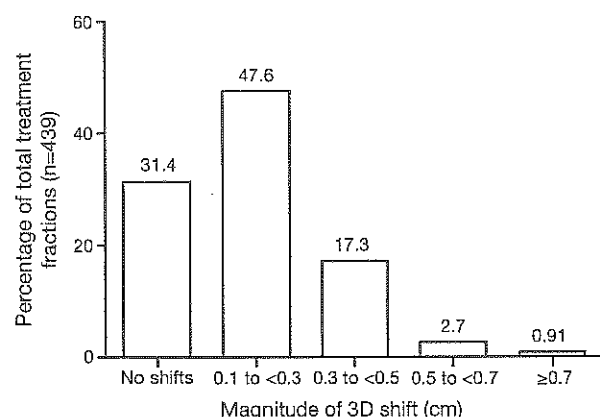


Figure 1 Histogram of the magnitude of 3D shifts required based on CBCT after patient positioning with plain fiducial marker kV radiographs. Based on 439 treatment fractions from 25 prostate cancer patients. "No shift" defined as less than 1 mm (<0.1 cm) shift. 3D, three-dimensional; CBCT, conebeam computed tomography; kV, kilovoltage.

literature suggests that this trend is not universal (12-15). One possible explanation is the daily prostate position shift caused by nearby organs such as the rectum and the bladder. Patients did not undergo daily bowel preparation prior to treatment and the amount of stool and gas in the rectum can certainly affect prostate positioning. In addition, patients were instructed to empty their bladder prior to simulation and treatment, but there is no effective way to standardize the post-void residual volume prior to simulation and treatment, especially considering many patients have enlarged prostates and voiding difficulties. A small study have investigated the bladder volume and prostate position changes using CBCT in patients who were instructed to keep their bladder full and found the bladder dimension to differ significantly in the inferior-superior direction but no significant shift in the target position (16). Further studies are needed to investigate the inter-fraction variability in size and shape of these surrounding organs that may explain our observation.

Fiducial-based imaging does not add any more time, radiation dose, or resources that are required for bony anatomy based imaging during a radiation treatment session. There have even been small studies that have reported on fiducial based imaging and its ability to reduce PTV margins (17). We believe that, in prostate radiotherapy, bony anatomy based alignment has inherent and significant limitations in localizing a soft tissue organ that is mobile

with respect to the nearby bony structures, and it is therefore reasonable to replace this alignment technique with fiducial based imaging. According to the American College of Radiology (ACR) Appropriateness criteria, daily localization of the prostate with implanted markers is more appropriate than bony anatomy for external beam radiation therapy for patients with localized prostate cancer (18). Our results continue to support the mounting evidence of improved target localization afforded by fiducial based imaging. However, larger studies with follow-up data are needed to assess if the benefit of target localization with fiducial markers actually translates into better clinical outcomes.

Prostate localization using CBCT has the theoretical advantage of providing better soft tissue delineation and accurately localizing fiducial markers in 3D view, which cannot be accomplished by kV imaging. This is potentially important when the patient's bladder and rectum sizes vary significantly on certain days of treatment. However, in the present study, we found only marginal benefit of CBCT for the alignment of implanted fiducials compared to kV radiographs. Residual mean shifts guided by CBCT were relatively small compared to kV imaging alignment (majority less than 0.3 cm). This small discrepancy in fiducial localization is to be expected due to the difference in target visualization between the two image registration methods and subtle patient motion while imaging is being obtained on treatment table and may not necessarily result in truly more accurate radiation delivery to the target organ. Shi *et al.* compared CBCT software-automated alignment to soft tissue markers *vs.* CBCT manual alignment to implanted fiducials, concluding that alignment to fiducials was the more accurate method (15). Barney *et al.* investigated CBCT-guided manual soft tissue alignment, comparing it to kV portal image-guided fiducial alignment (14). Although their data revealed that 60% of shift differences between these two methods were greater than 3.0 mm, the authors endorsed fiducial alignment based on CBCT-related increases in treatment times and the need for physician input for soft tissue alignment.

The greater length of time required for CBCT acquisition is likely not inconsequential, as studies have shown that the required margins for intrafractional motion increase with treatment time (19). In our study, the treatment time also significantly differed between the two groups, with CBCT patients taking on average 6 more minutes per treatment. Furthermore, CBCT increases overall patient exposure to ionizing radiation. Kan *et al.* reported that standard kV CBCT resulted in an effective dose of 22.7 mSv per scan to

the pelvis and that if used daily could increase the secondary cancer risk by up to 2% to 4% (20).

Because of the propensity for the prostate to shift within the pelvis, an imaging localization modality that identifies the organ itself appears to be superior and can potentially result in smaller margins to account for errors. While fiducial markers are a good way to localize the prostate, their use is not universal in practice of radiation oncology. In addition, insertion of the markers is not without its own set of complications and this should be taken into consideration (11). When fiducials are not present, Palombarini *et al.* found that, compared to bone alignment with CBCT, soft tissue alignment resulted in larger degree of AP shifts due to random shifts in prostate position. The authors concluded that CBCT's ability to see not only bony landmarks but also soft tissue gray scale allows for better localization of prostate in daily treatments and may reduce the PTV margins (21). This is especially important as the field starts moving towards more hypofractionated treatment, such as stereotactic body radiation therapy. In addition, CBCT imaging can offer the advantage of much better resolution of the pelvic structures, such as intra- or peri-prostatic calcifications, compared to plain films, which can be used as natural markers in select patients without the need to undergo invasive marker placement (22). Thus, CBCT may be more valuable in such cases where fiducials are not utilized. Large scale study directly comparing the use of fiducials in CBCT IGRT is warranted to further clarify which technique results in better outcome.

In interpreting the results of this study, several limitations must be addressed. Due to time constraints and resources available, CBCT was not universally done to all of the patients. This reduced the amount of data available in the CBCT group. As mentioned earlier, one of the advantages of CBCT is in its soft tissue resolution, allowing for assessment of not only prostate location but shape of surrounding anatomy, more frequent CBCT (daily with or without fiducial markers) could potentially provide more accurate treatment delivery. Another limitation of the study is its lack of clinical outcome with respect to disease control and toxicities. Future studies can potentially compare objective clinical findings and patient reported outcome to different target localization in order to assess the degree of benefit in more accurate treatments.

Conclusions

In conclusion, the results of this study indicate that

daily prostate localization using fiducial markers in kV radiographs during radiation therapy for prostate cancer may offer better target localization compared to patient bony anatomy alone. The addition of CBCT to did not seem to provide significant additional benefit if fiducials are already in use but is associated with increased treatment time and radiation exposure to the patients. CBCT may be more useful in cases where fiducials have been lost and there are less than three present, or in patients who are medically unable to undergo fiducial placement.

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All authors contributed to the design of the study. JC Ye was involved in all aspects of the study and co-wrote the paper. MM Qureshi performed the data analysis and was involved in interpretation of results along with assisting in writing the paper. P Clancy and LN Dise were involved in carrying out the treatment and collection of data. J Willins designed the method to calculate 3D shift and was involved in editing the manuscript. AE Hirsch supervised this study and was involved in all aspects of the study from study design to data interpretation and co-wrote paper.

Footnote

Conflicts of Interest: Presented in part at the 52nd Annual Meeting of the American Society for Radiation Oncology, Oct 31-Nov 4, 2010, San Diego, CA, USA.

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Reducing Use of Physical Restraint: A Pilot Study Investigating a Relationship-Based Crisis Prevention Curriculum

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The use of physical restraint in residential treatment programs continues to be a topic of debate. Yet, there is a scarcity of empirical research on effective methods for reducing both the need and the use of physical restraint. Without such evidence, there is no clear direction on how to improve staff practices when working with students experiencing emotional and behavioral challenges. Consequently, it has been difficult for programs to develop clear, consistent, and definitive efforts to reduce restraint practices and eliminate unnecessary restraint. In an effort to improve program practices, we designed and piloted a relationship-based crisis prevention curriculum. In this article we discuss the pilot study and briefly outline curriculum features. Pilot study results reveal a statistically significant reduction in restraint, a shift in attitudes about prevention and need for restraint, and a positive trend in staff preparation. Additionally, the social validity of the curriculum and future directions for practice and research are discussed.

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The use of physical restraint as a method of behavioral control when working with children and adolescents with disabilities has been a topic of debate for many years. Although behavioral management is challenging when working with children in residential settings, too often youth who are experiencing emotional crisis or display undesired behaviors are controlled through the use of physical restraint. Many have argued that excessive use of physical restraint has resulted in unnecessary tragic outcomes, including severe injuries and deaths. The *Hartford Courant* reported that physical restraint techniques used during crisis had resulted in 142 deaths in the United States over a 10-year period (Weiss, Altamari, Blint, & Megan, 1998).

In response to this report, the U.S. Government Accounting Office (USGAO) conducted a nonpartisan investigation of restraint use in federally funded mental health facilities. The results of this inquiry confirmed widespread misuse of restraint and alarmingly high rates of injury and death resulting from restraint procedures (USGAO, 1999). It also found that state level monitoring and reporting systems were inadequate and recommended that the U.S. Health Care Financing Agency (USHCFA) establish a set of clear regulations restricting the use of restraint procedures and mandated reporting requirements for all facilities receiving federal assistance. However, despite these recommendations, restraint procedures continue to be unregulated in many human service agencies including those that serve children (Norwood et al., 2011). The effects of poor regulatory structures were documented in a 2000 investigation by the Child Welfare League of America that estimated between 8 and 10 children in the United States die each year because of restraint procedures, while thousands suffer injuries that include damaged joints, fractures, and friction burns (CWLA, 2000). The fact remains that due to poor regulation, oversight, and policy, it is unknown how many deaths occur annually due to the use of physical restraint (Norwood et al.). What is known is that there is a high frequency of restraint cases that could have been avoided in residential settings (Norwood et al.; USGAO, 2008, 2009).

If children and adolescents placed in therapeutic residential settings experience emotional crises that result in emotional, psychological, behavioral, or physical dysfunction, then these children need trained caregivers who can assist to de-escalate their crisis without resorting to physical interventions. Newly hired caregivers employed in residential settings are typically provided a brief crisis intervention training that focuses primarily on techniques for physical restraint (Bud-Long, Holden, & Mooney, 1993). They seldom receive in-depth training on how prevent and/or de-escalate crisis situations. Bud-Long and colleagues have outlined that training is only one component in any residential programs effective restraint reduction efforts

(RRE). Instead, a systemic structure within the program that has access to a broader community of practice increases the likelihood of achieving successful RRE (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005). Fixsen et al. describe a community of practice (COP) model as a self-sustaining learning community in which caregivers, administrators, advocates, and researchers develop open and mutually beneficial partnerships that contribute to the ongoing development and refinement of a model, intervention, or collection of practices. Other evidence-based RRE components that integrate into a COP model are effective leadership and clinical oversight (Bud-Long et al.), ongoing supervision, and a supportive milieu (Allen, 2003; Miller, Hunt, & Georges, 2006; Paterson et al., 2003). Program milieu, which includes attitudes and beliefs on the use of restraint, quality and emphasis of training, and quality of the job environment is an especially important component of any RRE given that it has been found to be more strongly correlated with restraint use than child behavior (Miller et al.). Too often a program's milieu encourages caregivers to use restraint or the threat of restraint as a primary method of controlling behavior (Bath, 1994; Weiss, Altimari, Blint, & Megan, 1998). We believe such actions may prevent children with emotional and behavioral difficulties from trusting adults, further placing them at social, emotional, and academic risk.

The starting point for creating milieu that successfully reduces restraints includes the domain of staff preparedness. Given the federal conclusion that restraint is often misused *and* that restraint is a primary method for controlling crisis behavior, it would appear that the content, emphasis, and quality of staff preparation continue to need drastic revision. Historically, staff preparation has taught three criteria in the application of a restraint—harm to self, harm to others, and damage to property. More recently, many state statutes and regulations have adopted a higher standard; that physical restraint is only to be used as a last resort when less restrictive de-escalation techniques are no longer effective and the child is in imminent danger of harm to self or others (Tovino, 2007). Nonetheless, the moral, ethical, and technical issues surrounding restraint are far from settled, with no consensus on best practices for RRE. Furthermore, despite such a long history of legal and ethical controversy there has been an absence of good research on crisis prevention and intervention practices (Day, Daffern, & Simmons, 2010).

In residential settings, the centerpiece of most RREs is crisis intervention training. Typical trainings cover basic verbal and non-verbal de-escalation techniques; very specific techniques on blocking punches, bites, hair pulls; and guidelines on how and when to use physical restraints. A review by Couvillon, Peterson, Ryan, Schuermann, and Stegall (2010) revealed that the most popular crisis intervention trainings used in residential facilities place the majority of emphasis on how to perform physical restraints, leaving very little time for instruction in proactive, preventative methods to de-escalate crisis situations. Such a time ratio of physical techniques to de-escalation

skills suggests that widely used crisis intervention curricula provide little to no information on how to build, maintain, and assess the quality of a child-caregiver relationship; processes that are, in our belief, the pillars to any de-escalation effort with a child in crisis.

PROACTIVE, RELATIONSHIP-BASED DE-ESCALATION

Researchers have suggested that placing an emphasis on the establishment of high quality, trusting caregiver-child relationships may assuage the life-long difficulties and problems many children and youth with emotional or behavioral difficulties face (Davis, 2006; Hamre & Pianta, 2001; Meehan, Hughes, & Cavell, 2003). Pianta (2001) characterized caregiver-child relationships as containing the dimensions of conflict, closeness, and dependency. Because relationships are crucial to social-emotional and academic competence (Pianta, 2000), and conflict-oriented relationships have been shown to contribute to social-emotional difficulties (Nelson & Roberts, 2000; Van Acker, Grant, & Henry, 1996), an emphasis upon developing trusting relationships between caregivers and children can be seen as a viable intervention for reinforcing positive social, emotional, and academic development (Brendtro, Brokenleg, & Van Bockern, 2002; Long, Morse, Fecser, & Newman, 2007; Vitto, 2003). In particular, students identified as experiencing emotional or behavioral difficulties, who also experience sustained positive relationships, have demonstrated significantly improved social, emotional, and academic outcomes and, as a result, fewer crisis events (Murray & Greenberg, 2001; Pianta, Belsky, Vandergrift, Houts, & Morrison, 2008).

The application of research on the therapeutic value of relationship building between children and caregivers can be seen in two training interventions that show promise in de-escalation efforts during crisis situations: (a) training caregivers to place a strong emphasis on developing early high, quality relationships (see Amos, 2004) and (b) using cognitive behavioral modification training to change caregiver thinking about interactions during crisis situations (see Singh et al., 2006). Cognitive-behavioral modification (CBM) rests on the premise that personal thought, in conjunction with and influenced by reinforcement history, play a critical role in determining one's behavior (Meichenbaum, 1977; Vygotsky, 1962). In essence, caregivers who think about their interaction patterns and invest in high quality relationships with clients have a better chance to de-escalate an emotionally charged, crisis situation.

PURPOSE OF THE STUDY

Recently we completed a pilot study exploring a conceptually new approach to crisis intervention training emphasizing trusting interactions that build high

quality relationships between practitioners and children with emotional and behavioral challenges. Given that there is a paucity of research on crisis intervention trainings in residential programs (Day et al., 2010) and that most crisis intervention trainings focus primarily on physical techniques (Couvillon et al., 2010), it seemed worthy to design and field test a relationship focused, CBM-based curriculum's impact on RRE.

Hypothesis and Research Questions

We hypothesized our investigation would directly impact the frequency of physical restraint implemented by caregivers working with students who experience emotional, behavioral, and mental health issues. Specifically, by fostering a COP dedicated to crisis prevention and training staff in proactive, relationship-based crisis intervention techniques, overall program milieu and interaction patterns would change such that there would be a higher degree of trust between caregivers and children and fewer conflictive interactions leading to inappropriate use of restraint. In addition we believed that by providing specific techniques to de-escalate emotionally charged crisis situations and improve overall interaction patterns with clients, frontline caregivers would feel better prepared and change their perceptions and attitudes toward use of restraint. Such changes in beliefs would directly impact the milieu of the program, resulting in an environment that was less coercive and more cooperative. Our research questions were as follows:

- Can *Shifting Gears*, a relationship-based approach to crisis intervention training, reduce the frequency of physical restraint used on youth in a residential program?
- Can *Shifting Gears* change overall staff knowledge of pro-active, preventative strategies and perceptions of intervention preparedness, attitudes toward restraint, and improvements in the job environment?
- Can *Shifting Gears* change staff perception of crisis intervention preparedness, attitudes toward restraint, and overall job satisfaction?

METHODS

Setting and Sample

The curriculum was piloted in a therapeutic residential wilderness treatment program for boys located in the Southeastern United States. On average, the program houses 45–55 boys between the ages of 12 and 17. The average length of stay for a camper is 6–9 months. Residential placement was due to emotional or behavioral difficulties, substance abuse problems, and sexual offenses. Educational experiences occur throughout the day via structured

TABLE 1 Demographic Characteristics of Respondents

Characteristic	<i>n</i>	%
Current position		
Caregiver/Consumer support staff	20	50.0
Case manager	1	2.5
Social worker/Psychologist/Counselor	3	7.5
Supervisor/Director/Administrator	7	17.5
Teacher	4	10.0
Other	5	12.5
Gender		
Male	23	57.5
Female	17	42.5
Years of experience		
0–5 Years	16	40.0
6–10 Years	6	15.0
11–15 Years	7	17.5
16–20 Years	5	12.5
21 Years or More	6	15.0
Ethnicity		
White/Non-Hispanic	26	65.0
African-American	10	25.0
Native American	1	2.5
Other	3	7.5
Education status		
High school graduate or GED	14	35.0
Associate's degree	4	10.0
Bachelor's degree	15	37.5
Master's degree	7	17.5

activities and a few hours a day with a certified teacher. Occasionally groups of boys and direct care workers venture off site for extended camping excursions. Each resident is placed within six groups who live in campsites with two to three direct care workers. There is approximately 60 staff, of which 35 are described as direct care workers. Of the direct care workers; those who live with the boys in campsites experience a high attrition rate averaging five per month.

Although all staff received the *Shifting Gears* training, a sample of 40 staff participated in the pre-post assessment. The majority were direct care staff (caregivers/consumer support staff) and most had 5 years or less experience in their positions. Just over a third of respondents had a high school diploma or GED, while ~38% had a Bachelor's degree. See Table 1 for a full description of sample characteristics.

Procedures

This therapeutic residential wilderness treatment program was selected from a participant pool from a previous survey sent to all residential program

administrators within a Southeastern state who had: (a) an on-site crisis intervention trainer and (b) indicated that their staff had a willingness to change. We selected the program because of the presence of on-site trainers to best facilitate a community of practice (COP). Refining the selection criteria further through reported willingness to change seemed a logical way to detect any change in RRE. Upon selecting the pilot program, the existing crisis intervention trainers were trained in the new curriculum by a research team. We assessed treatment fidelity by observing approximately 30% of lessons taught using checklists corresponding to adherence of lesson content. A portion of these observations (20%) was collected using trained research assistants for reliability of observations. Treatment fidelity training for any observer consisted of an overview of curriculum features, examples of curriculum content, and scoring of treatment fidelity forms. Training occurred until an IOA (Inter-Observer Agreement) of 95% was achieved.

We used a case study design to evaluate the curriculum's effect on RRE. Given the high rate of direct care worker turnover, pre intervention frequency of restraint data was taken for 4 months before staff was trained in the curriculum and continued 4 months after training. Additionally, we administered a pre-post survey of staff to evaluate a change in milieu via staff perception of crisis intervention preparedness, attitudes toward restraint, and overall job satisfaction.

Intervention

The intervention used in this study is a crisis intervention curriculum called *Shifting Gears: Conflict Avoidance through Working Partnerships*. It is a proactively designed curriculum that improves interactions between children and caregivers and provides emergency techniques for crisis situations. *Shifting Gears* was developed with input from multiple stakeholders over a 3-year period with the support from the North Carolina Department of Health and Human Services (NCDHHS). This crisis intervention training, unlike others, places greater emphasis on building trusting relationships from day one. Our conceptual framework for the *Shifting Gears* curriculum is an adaptation of Pianta's (2001) *Student-Teacher Relationship Scale (STRS)*; an instrument used by teachers to rate pre-Kindergarten through third grade students. The *STRS* factors relationships into the relational dimensions of closeness, conflict, and dependency. We expanded these dimensions to caregivers and teachers who work with a wider range of children. Additionally, the curriculum includes easily remembered acronyms that allow caregivers to (a) gauge and assess the quality of relationships, (b) improve or maintain high quality relationships, (c) self-regulate their emotions through the use of a CBM, and (d) de-escalate a crisis situation while preserving the relationship.

The 18–20 hour training begins with three units focused on crisis prevention: Unit I, entitled “A Close, Trusting Relationship is the Best Prevention,” focuses on developing working partnerships with clients as the first and most important component of a crisis prevention system; Unit II, entitled “People in Crisis,” provides a discussion of the many factors that influence crisis behavior; and Unit III, entitled “Filling Your De-Escalation Toolbox,” contains content and exercises designed to help caregivers develop skills for calming agitated clients. The following section, entitled “Emergency Techniques: The Last Tool in the Toolbox,” focuses on a carefully selected set of physical interventions that are presented as last resorts for assuring client and caregiver safety. The curriculum concludes with a review of Units I–III, which contains a review of prevention skills and practices. Finally, a chapter written solely for trainers provides an overview of effective teaching practices and a collection of trainer tips and resources. Additionally, there is a unit written for administrators that summarizes the concepts within the curriculum, encourages building a COP, and suggests ways to promote staff to shift to a more relationship based approach when working with children. Included below are specific features of *Shifting Gears*.

- Applied strategies: *Shifting Gears* provides caregivers strategies for de-escalation and tools to assess interactions to build or maintain relationships during emotional crisis.
- Adult oriented activities and resources: *Shifting Gears* includes an extensive collection of carefully selected adult oriented activities and resources. These materials were chosen for their effectiveness at engaging a broad range of caregivers. This includes visual and experiential concepts, cognitive-behavioral based self-calming techniques, easy to remember acronyms, discussions, self-directed learning, realistic scenarios, role-plays, icebreakers, and games to convey key ideas.
- Improved flexibility: Each unit in *Shifting Gears* contains a section on differentiation that includes suggestions for participants working with specific groups (e.g., mental health, developmental disability, and substance abuse) and age ranges (e.g., children, adolescents, adults, and seniors).
- A refined physical techniques section: The section covers emergency techniques and excludes procedures that have been deemed either ineffective or potentially hazardous.
- A closing unit on crisis prevention: The concluding chapter of *Shifting Gears* contains a review of prevention concepts and practices. This unit is unique to crisis prevention curricula in that it was developed so that participants would end the training with a focus on prevention rather than emergency physical intervention techniques.

Measures

To examine the efficacy of *Shifting Gears*, we used the following measures:

- Frequency of restraints: We collected monthly data on the frequency of restrictive interventions (physical restraints).
- Pre/post caregiver survey: This survey was designed to measure milieu change in (a) staff's knowledge of de-escalation techniques, (b) attitudes toward restraint, (c) evaluation of and experience with crisis intervention training, and (d) basic demographic information (e.g., years working with children, education level, number of trainings attended, etc.).
- Fidelity checks: We observed 20% of all trainings, of which 10% consisted of four trained observers for inner observer agreement.
- Social validity: Qualitative staff reports and summary means and standard deviations from the *Shifting Gears Pre/Post Caregiver Survey* were used to answer questions regarding curriculum efficacy and ease of use.

Procedures for Data Collection

Four months before training, we began collecting monthly data on frequency of restraints in the program as well as administered the *Pre/Post Caregiver Survey*. During training fidelity checks were conducted. Once training ended, we continued collecting data on frequency of restraints. Four months post-training, we again administered the caregiver survey, including social validity measures.

Treatment Fidelity

We assessed treatment fidelity by observing approximately 30% of lessons taught using checklists corresponding to adherence of lesson content. A portion of these observations (20%) was collected using trained research assistants for reliability of observations. Treatment fidelity training for any observer consisted of an overview of curriculum features, examples of curriculum content, and scoring of treatment fidelity forms. Training occurred until an IOA (Inter-Observer Agreement) of 95% was achieved.

Data Analysis

FREQUENCY OF PHYSICAL RESTRAINTS

The total frequency of physical restraints from each month was recorded on the first day of the preceding month (e.g., all October physical restraints recorded on November 1). The monthly data were then graphed to assess within and between phase patterns in the data. Specifically, we examined the graph for within and between level-change from pre- to post-intervention, overall trend, and variability.

PRE/POST CAREGIVER SURVEY

First, descriptive statistics were used to assess overall responses across all survey items pre and post. Next, we summed scores (e.g., 0 for incorrect and 1 for correct) across the eleven knowledge items in Section 2 of the survey and calculated summed scores for Sections 3 and 4 based on respondents' ratings of restraint training and perceptions of restraint and perceptions of the job environment. For Section 3, we summed the following items: (a) "Rate the overall effectiveness of your past trainings in crisis intervention," (b) "Rate how well your trainings have prepared you to de-escalate a client in crisis," (c) "Rate how well your trainings have prepared you to use physical interventions for a client in crisis," (d) "In my opinion, physical restraint should only be used when there is no other alternative to assure client & staff health & safety," (e) "In my opinion, most physical restraint can be prevented." All items were rated on a six-point Likert scale, with a score of "two" representing poor perceptions of training and that restraint cannot be prevented and a score of "five" representing excellent perceptions of training and perceptions that restraint can be prevented (a score of "one" represented not applicable, however, no respondent used this rating). Section 4 of the survey included eight items that asked respondents to rate their job environment based on a four point Likert scale with "four" representing a positive job environment, while "one" represented a poor job environment. Reliability of the three summed scores was evaluated based on the preassessment period. Reliability for the knowledge section was $\alpha = .74$, $\alpha = .76$ for the training section, and $\alpha = .89$ for the job environment section.

We used paired samples *t*-tests to assess whether or not respondents' knowledge increased from pre to post, whether perceptions of restraint training increased, and whether or not perceptions of the job environment increased. In addition, we calculated paired samples *d* effect sizes (Cohen, 1988) for each of the three sections. Last, we calculated a regression model for each of the sections to assess differences by respondent characteristics. Due to the small sample size, the regression models used difference scores (i.e., post summed score minus pre summed score) for the dependent variable. Difference scores are not recommended when the pre and post values are significantly correlated (Edwards, 2001), which was not the case in this study for two of the three sections ($r = .28$ for knowledge, $r = .21$ for training, and $r = .40$ for job environment). Therefore, the job environment results should be interpreted with caution. The regression models included respondents' experience, education, position, and gender as covariates. All variables were transformed into dichotomous variables for ease of interpretation. "Experience" compared respondents with 0–5 years of experience to six or more years, "education" compared respondents with only a high school diploma to those with any postsecondary education, and

"position" compared direct care staff (e.g., caregivers/consumer support staff) to all other positions.

RESULTS

Physical Restraint

Visual analysis of the monthly frequency of physical restraint results indicates a decreasing trend in the frequency of restraints from November 2013 to June 2014 (see Figure 1). Training occurred for all staff from February to March. The average monthly frequency of restraint prior to the training was 17.3 incidents, while the average monthly frequency following training was 5.5 restraint incidents. Although the decreasing trend confounds the interpretation in that the decrease could have continued, the average monthly decrease pre- and post-training are encouraging.

Pre/Post Caregiver Survey

Overall, item-level responses increased by 35% from pre to post for the knowledge section of the survey. The largest changes were for correctly identifying the cognitive behavioral modification acronyms used to assess relationship quality and determine the level of restrictive intervention required. Some changes were evident from pre to post with respect

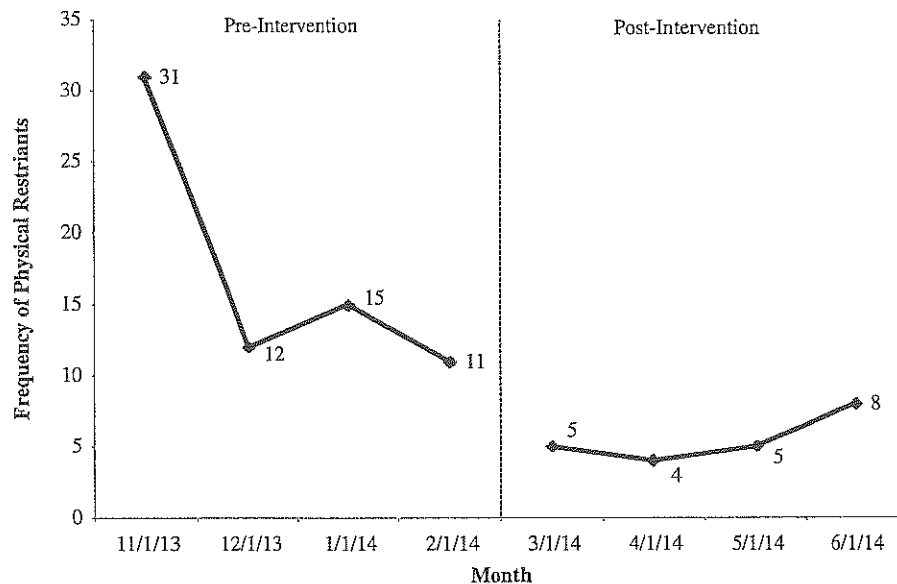


FIGURE 1 Frequency of physical restraints by month.

to responses on the perceptions of training and prevention of restraint. For example, 10% of respondents changed their rating of training effectiveness to good or excellent, while 23% increased their perceptions of preparedness to intervene to good or excellent during the post survey. Very few changes were found from pre to post with respect to perceptions of the job environment.

Differences from Pre to Post

To assess whether or not survey respondents improved their knowledge of crisis prevention and intervention, the survey included eleven correct/incorrect items, seven fill in the blank and four multiple-choice (see Table 2). To determine whether or not respondent knowledge of crisis prevention and intervention increased from pre to post, a sum score was calculated for each respondent based on whether or not they answered each of the 11 items correctly. The summed score had a maximum value of 11. During pre-test, the average sum score was 1.0 ($SD = 1.4$), with a range of 0.0–5.0, indicating that respondents got only one question correct. At post-test, the average sum score increased to 4.8 ($SD = 2.4$), with a range of 0.0–9.0. To identify whether or not the pre-post increase was statistically significant, a paired samples t -test was calculated. Results indicated that respondents' knowledge of crisis prevention and intervention increased significantly, with mean difference of 3.8, $t = 9.9$ ($df = 39$), $p < .000$.

Five items were summed to assess perceptions of restraint training and the prevention of restraint from pre to post. The summed scores had a maximum value of 30, representing positive perceptions of the training respondents received on restraint and prevention of restraint. During the pre-assessment, the average training score was 20.3 ($SD = 4.9$), with a range from 10 to 27. During the post assessment, the average training score was 22.9 ($SD = 2.8$), with a range of 14–28. Results indicated that respondents' knowledge of crisis prevention and intervention increased significantly, with mean difference of 2.6, $t = 3.1$ ($df = 39$), $p < .004$.

Eight items were summed to assess perceptions of the job environment from pre to post. The summed scores had a maximum value of 32, representing positive perceptions of respondents' job environment. During the pre-assessment, the average job environment score was 15.6 ($SD = 4.9$),

TABLE 2 t -Test Results for Pre-Post Differences for Overall Section Scores

	Pre		Post		df	t	p	G
	M	SD	M	SD				
Overall section								
Knowledge	1.0	1.4	4.8	2.4	39	9.9	.000	1.56
Training	20.3	4.9	22.9	2.8	39	3.1	.004	0.49
Job environment	15.6	4.9	14.0	3.3	38	-2.1	.040	-0.34

with a range from 8 to 27. During the post assessment, the average training score was 14.0 ($SD = 3.3$), with a range from 8 to 21. Results indicated that respondents' perceptions of their job environment decreased from pre to post and that that decrease was statistically significant, with a mean difference of -1.6 , $t = -2.1$ ($df = 38$), $p < .040$.

Differences by Respondent Characteristics

Three regression models were calculated using difference scores for each of the sections. The knowledge difference score had a mean of 3.83 ($SD = 2.44$), with a range of -1 to 9; the training difference score had a mean of 2.53 ($SD = 5.15$), with a range of -11 to 13; the job environment difference score had a mean of -1.61 ($SD = 4.65$), with a range of -14 to 7. The regression model for the knowledge difference score accounted for 22% of the total variance and was statistically significant ($F = 3.75$, $df = 4,35$, $p = .012$). Results for the predictors are available in Table 3. Education was a significant predictor in the model, indicating that, on average, respondents with any postsecondary experience significantly increased their knowledge score compared to respondents with only a high school education. The regression models for training ($R^2 = .00$, $F = 0.87$, $df = 4,35$, $p = .492$) and job environment ($R^2 = .02$, $F = 1.16$, $df = 4,35$, $p = .346$) were not significant, indicating that respondent characteristics did not predict any differences in responses from pre to post.

Treatment Fidelity and Social Validity

Based on teacher reports and observational data, teachers implemented *Shifting Gears* with a high degree of fidelity. Of the lessons observed, treatment fidelity was 100%. Moreover, the average observer-rated treatment fidelity across trainings was 100%, indicating that both trainers followed the curriculum as prescribed.

Overall, all staff trained reported that *Shifting Gears* is a socially valid curriculum for dealing with emotional crisis, de-escalating students, and was better than previous crisis curriculums they experienced. On site trainers reported the curriculum was easy to use and that the curriculum was appealing and useful at their program. Trainers also provided feedback used to further revise the curriculum for improved ease of use. Anecdotal data further supports the social validity of the curriculum in that the agency was enthusiastic about the curriculum as evidenced by making t-shirts using curriculum logo for staff, posted signs around the facility, used curricular terminology during meetings, and in two cases fired those unwilling to adopt the principles within the curriculum. Additionally, the program would have used the curriculum for the study period and returned to the existing curriculum

TABLE 3 Regression Models With Respondent Characteristics Predicting Difference Scores

Predictor	Knowledge					Training					Job environment				
	B	Std. Err.	β	<i>t</i>	<i>p</i>	B	Std. Err.	β	<i>t</i>	<i>p</i>	B	Std. Err.	β	<i>t</i>	<i>p</i>
Experience	0.76	0.84	.15	0.90	.374	1.37	2.01	.13	0.68	.500	-1.94	1.83	-.21	-1.10	.296
Education	2.59	0.78	.51	3.30	.002	-3.10	1.87	-.29	-1.66	.106	1.40	1.70	.15	0.82	.416
Position	0.46	0.85	.10	0.54	.596	0.84	2.05	.08	0.41	.684	0.05	1.90	.01	0.03	.980
Gender	0.03	0.78	.01	0.04	.965	2.36	1.87	.23	1.26	.215	2.25	1.72	.24	1.31	.200

Note. Std. Err. is standard error of beta.

afterward, just to have a better curriculum temporarily. As it turned out, the program is still using *Shifting Gears*.

DISCUSSION

This pilot study explored the impact of a conceptually new approach to crisis intervention training emphasizing trusting interactions that build high quality relationships between practitioners and children with emotional and behavioral challenges. The results suggest that *Shifting Gears* may have contributed to decreased use of physical restraint, increased knowledge about prevention and proactive strategies to reduce the use of restraint, and improved perceptions about the effectiveness and importance of crisis prevention and intervention trainings.

A central focus on the *Shifting Gears* program is the reduction of restraint and seclusion. We collected monthly frequency counts of restraint use at the therapeutic wilderness program and found difference in the average number of restraints used pre and post training. However, the results are not clear, as a decreasing trend was present during the months prior to implementation of *Shifting Gears*. A potential explanation for the decreasing trend during the pre-intervention phase is that the COP started in December and was occurring as the trainers were being trained in the curriculum and ideas were introduced prior to training all staff. In other words, the decrease in monthly restraint use could have the result of training the trainers who also served as lead staff in the program who also used restraint.

In this pilot study, we also examined pre-post differences in the knowledge of pro-active, preventative strategies and perceptions of intervention preparedness, attitudes toward restraint, and improvements in the job environment. The results suggest that, on average, attending *Shifting Gears* increased staff knowledge of preventative strategies to reduce the need for restraint. The large effect size indicates that the training was very effective and increased knowledge of preventative strategies. *Shifting Gears* also appeared to increase staff's perceptions about the quality and effectiveness of restraint and seclusion training. The moderate effect size suggests some variability, but overall, promising impacts on staff perception. The results for changes in perceptions of the job environment were not as expected and results indicated that staff had lower perceptions of the job environment following the *Shifting Gears* training. No follow-up was conducted with the staff, but we hypothesize that the decrease in perceptions of the job environment may be due to a high turnover rate of direct care staff. When a new hire begins working with students who experience emotional and behavioral challenges one may predict that their job ratings would be lower than overall staff ratings. Additionally, novice direct caregivers may find the job initially

challenging explaining lower ratings of job satisfaction and contributing to high turnover (Knudsen, Ducharme, & Roman, 2006).

Considerations for Research

The results of this case study are promising, but should not be over interpreted. In order to assess the impact of the program on both reduction of restraint use and perceptions of the job environment, a more rigorous study employing a quasi-experimental or randomized experimental design with treatment and control groups is necessary. In addition, future research should include measurement of caregiver-client relationships, which could include pre/post surveys of both direct care staff and the students they serve.

In addition to replication with more rigorous designs, extensions of this case study should be considered. Specifically, assessing differences in effectiveness by the population served (e.g., students with severe intellectual disabilities) and settings they are in (e.g., juvenile justice). It may also be necessary to assess differential impacts for varied milieus (e.g., facilities less willing/interested in changing) and whether or not program staff volunteer to participate or are mandated to participate. Finally, when surveying staff with high turnover methodological and longitudinal approaches should be considered. Overall, much more research is necessary to draw conclusions about the effectiveness of *Shifting Gears*, but we believe this study highlights the potential for positive future impacts.

Considerations for Practice

Although results of curricular effects during this pilot study should be interpreted with caution and more research is needed, there are still some considerations for practice with respect to RRE.

TRAINING CONSIDERATIONS

When considering survey results, variables such as (a) increased knowledge and (b) change in perceptions of training quality, views on restraint practices, and preparedness in de-escalation techniques may have contributed to the program's successful RRE. Given that there was increased knowledge on curricular concepts representing a relationship-based approach through the use of CBM-based acronyms, there is promise that such concepts are useful in trainings. Specifically, when providing training to adult learners, conceptualizing key ideas as easy to remember acronyms may allow for easy recollection and application in crisis situations. Additionally, caregivers and staff successfully learned a greater variety of specific techniques in

de-escalation when compared to pre-intervention. Crisis intervention trainings that provide information for a diversity of educational levels, visual imagery, mnemonics, CBM, case studies, multiple exemplars, and roles plays when presenting content may provide adult learners a deeper understanding of de-escalation and potentially enabled them to avoid unnecessary restraint.

With respect to positive staff perceptions of training quality, preparedness in de-escalation, and the prevention of restraint, selecting crisis trainings that are viewed as useful and effective by staff may contribute to a program's successful RRE. We suggest selecting crisis intervention trainings that explore staff attitudes, views, and beliefs as a promising practice that contributed to the pilot program's overall milieu and RRE. Perhaps because the *Shifting Gears* training ends with review of de-escalation techniques, staff were not left with lasting memories of the most restrictive physical techniques but, are instead, reminded of less restrictive interventions. If this planned curricular feature contributed to the pilot program's RRE, then crisis intervention trainings should consider not only initially placing more time and emphasis on how to de-escalate, but also end trainings with de-escalation techniques.

ADMINISTRATIVE CONSIDERATIONS

In part, the successful RRE during this pilot study was due to the supportive administration, therefore we recommend that program administration should embrace and understand the underpinnings of the curriculum they provide to their staff, attend trainings, and demonstrate and model curricular concepts. Beyond any training program, administrators and leaders should regularly place a greater emphasis on the client-caregiver relationship. Such actions will contribute to the overall milieu and affect the quality of interactions with students and staff. We suggest administrators should provide a minimum of bi-annual trainings that emphasize high quality interactions to bolster RRE.

Administrators set the tone for the culture and milieu of the program, yet there is no reason to "go it alone." We recommend that, when possible, administration should seek high quality trainers, collaborate with external agencies and resources, and encourage open communication within their staff. Such actions will promote or maintain an effective COP and support any program goals, such as fostering high quality relationships between caregivers and students.

While a supportive administration is critical to any RRE, it is important to note several important roles on the part of the administrator. First, a collaborative and safe debriefing with staff after any physical restraint is essential for staff growth, reflection to review if indeed the restraint was necessary, and assist in the prevention of future incidents. Second, collecting monthly data on frequency of restraints within the program is an important role of any administration. Such procedures allow a program to note how many students are involved in restrictive interventions and which students and

staff are involved. This information allows administration to target specific de-escalation efforts to reduce the difficulties with that student and improve staff practices. Finally, hiring staff that demonstrates characteristics aligned with the facilities milieu (e.g., relationship based) may insure the most therapeutic experience for students and aid in any RRE. In addition, we believe job satisfaction decreased from pre to post intervention because of the high direct care staff turnover. This study included staff that remained in their position for the duration of the study, yet we know anecdotally that there was high turnover and the new staff could contribute to the survey respondents' decreased perceptions of the job environment. Residential settings characteristically have a high rate of turnover for front line staff. In part, providing new staff with initial training and ongoing support while in the field may prevent such high turnover and provide them a better sense of job satisfaction.

POLICY CONSIDERATIONS

While the debate over the use of physical restraint is ongoing, it is clear that many cases can be avoided. One reason restraint remains contentious and debated is in part due to a lack of clear regulation, oversight, and policy. Although it has been established that restraint may only be used as a last resort when a child is in imminent harm to self or others (Tovino, 2007), most staff post-test responses indicated three reasons, including damage to property. Staff responses may suggest that programs will adapt rules as external guidance and support remains unregulated. Debate over the use of restraint, particularly how, when where, and is restraint therapeutic or not is still unclear. Additionally, a greater emphasis should be placed on informing programs and caregivers that physical restraint should only be used when a client is in imminent harm to themselves or others. The notion that a restraint can be used for damage to property is antiquated and needs to be eliminated from the knowledge base within the mental health field.

LIMITATIONS

A number of limitations necessitate mention. First, this was a case study and there was no comparison group. We believe that this was an appropriate approach to pilot the curriculum to assess ease of use, length of time, and acceptability. The next steps in our evaluation will include a comparison group. In addition, this study was conducted in only one type of therapeutic program limiting generalization of findings. Lastly, although we hoped to have pre/post-test and follow up data for every participant that received the training, staff turnover significantly reduced our sample size.

CONCLUSION

This initial investigation of our curriculum within a therapeutic wilderness residential treatment program that serves children with mental health, emotional difficulties, and sexual disorders, was designed to assess the effects between a proactive, relationship-based approach to crisis intervention and the reduction of physical restraint and improvement of program milieu. The results are promising. Yet, more research across a wide array of settings, resulting in practices that yield fewer restraints and improve therapeutic value, is still needed. We feel it is important to further investigate how high-quality relationships with students lay the foundation for any de-escalation effort. We believe that the field should continue to gather empirical evidence on the effectiveness of interventions like *Shifting Gears* with the goal of preventing future injury and death as well as improve overall quality of life for caregivers and students with emotional and behavioral difficulties.

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Kairos: The Right Time for the Laboratory as Educational Model

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We are all familiar with the Greek concept of *chronos*, or chronological time, of which we too often lament there is not enough. Perhaps we should embrace the other Greek concept of time: *kairos*, or the right time, the time when something remarkable is about to happen. As I believe about UDL, I believe that now is the right time for higher education to distinguish itself by becoming, from its leadership to its staff and students, a laboratory for learning. To date, probably because chronological time has allowed other things to get in the way, higher education has failed to realize the potential of a laboratory approach across campuses. Taking advantage NOW of these crucial missed opportunities—if explored, developed, and then implemented and assessed—can alter in the most positive way both how education happens and how an institution operates. Higher education can apply a laboratory approach to everything that is undertaken inside and outside the classroom. We can experiment, reflect, and write about what we do institutionally and in our living and learning communities. We can encourage imagination and problem-solving. We can even recognize the cost-benefit importance of utilizing students as resources and of interdisciplinary as well as inter-professional programming.

To be fair, higher education has attempted some of this in fits and spurts across the country. Sadly, though, the truly rich idea of laboratory learning (i.e., *praxis*, or connecting theory to practice) has ended up becoming associated with remediation. So, we need an architecture that explains our approach, guides our decisions, informs our teaching and pedagogy, and articulates a vision for campus life. Laboratory teaching and learning should become the staple for higher education. If successful, we will have found a way of reaching a wide range of students, credentialing individuals prepared as thoughtful, engaged leaders.

To extrapolate from MIT's Neal Lerner (whose book, *The Idea of a Writing Laboratory*, treats the possible future role of the writing laboratory), laboratories are alternatives to lectures and 'recitation'; they elicit and respond to hands-on learning

and social interaction among students with each other and collectively among faculty and staff and students. As Lerner and others have noted, the early and recent proponents of the laboratory approach to science and the early supporters of the laboratory approach to teaching writing offer a challenge for educators: take the best of laboratory learning and extend it to ALL disciplines—now and in the future (Agassiz, Dewey, Genung, Moore, Parkhurst). We should think about laboratories in healthcare, in the liberal arts, in the physical sciences and social sciences, in fitness, in business. In a nutshell, laboratory education, at its best, involves teaching and learning "as an experiment in possibility," to use Lerner's terminology.

Laboratories are places where risk-taking occurs, where mistakes can be made safely, where learning from errors is encouraged (indeed fostered), where getting it right the first time is less important than learning while doing over time. The central notion of experimentation inherent in the idea of a laboratory can offer ALL learners and teachers the opportunity to initiate profound reform and a common pedagogical orientation.

Laboratories acknowledge the social nature of learning and encourage collaborative learning. As UDL advocates stress, when we put our students in Vygotsky's "zone of proximal development," we create tasks that are challenging enough that one student on her own struggles to complete, but no so challenging that two or more students, working collaboratively, cannot complete efficiently and effectively. As Kenneth A. Bruffee wrote, "a necessary intermediate step on the way to effective independence is effective inter-dependence" ("Preface to the Third Edition").

A laboratory model will adjust what happens in class to allow collaborative learning, the nature of coverage to encourage deep learning, and the approach for assigning grades to reward mastering the process of learning. It alters teacher and student preparation; it changes our approach to teaching and learning. It suggests ways of shaping residential and commuter lifestyles.

It offers repeated opportunities for reflection. It alters expectations. The outcomes generated by laboratory learning are supported by associations like the AAC&U, which calls for inquiry, experimentation, and cross-disciplinary alliances (cf. Greater Expectations).

Making colleges and universities laboratories of lifelong learning can address three critical issues in higher education: (1) the so-called crises in literacy and technical proficiency as colleges and universities lament the preparedness of their students; (2) the lack of resources which complicates (and sometimes thwarts) innovation and experimentation; and (3) the inability to realize the imaginative possibilities that rest within a diverse student population, most particularly those who have social, economic or class differences, and the challenges of making progression through college both possible and relevant for first-generation students, career-changers, and other non-traditional learners.

The question is not whether laboratory learning makes sense. Instead, the question is whether we are courageous enough to embrace a different approach to learning and make laboratory learning THE central piece of our higher educational model—and to employ the principles of the laboratory across the curriculum and across the nation. All that impedes us is our willingness to try. We should get ready, to “don those white coats and safety glasses and discover what works” in order to affirm that “teaching [. . . is] a way of offering meaning-making opportunities for students no matter the subject matter” (Lerner). It is a risk well worth taking for, as some have observed about the laboratory approach to learning in disciplines such as writing, “the idea promotes ‘possibility’ and ‘productive chaos’” (Spigelman and Grobman).

Laboratory learning, within and outside the classroom, provides a frame for the good work of higher education. If we act now, if we accept the concept of *kairos*, the right time, we will do more than help our current students. We will be sustaining higher education for the future. We will be a laboratory experiment that works—for students, for faculty, for staff, and in the larger higher education community.

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SALVATION IN "CATHOLIC BOSTON":
FATHER LEONARD FEENEY AND SAINT BENEDICT CENTER, 1941-1949

A Dissertation

by

KATHERINE M. RICHMAN

submitted in partial fulfillment of the requirements

for the degree of

Doctor of Philosophy

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ABSTRACT

SALVATION IN "CATHOLIC BOSTON": FATHER LEONARD FEENEY AND SAINT BENEDICT CENTER, 1941-1949

Katherine M. Richman
Primary Advisor: Thomas E. Wangler

The story of the transformation of St. Benedict Center in Cambridge, Massachusetts, originally a small Catholic student center, into a controversial and socially disruptive religious community is little known today even by most Bostonians. Some sixty-five years ago, however, the Center's public activities under the leadership of its chaplain, Leonard Feeny, S.J., were the focus of intense controversy and publicity, nationally and internationally as well as locally.

In the 1940s, there was no clear theological consensus on the possibility of salvation for non-Catholics. Although there seems to have been a notable hesitation on the part of theologians and hierarchy alike in Boston to issue an official pronouncement on the Church's theology of salvation, there was at the same time an unhesitating consensus among them that Fr. Feeny's rigorist interpretation of the Catholic doctrine *extra ecclesiam nulla salus* ("no salvation outside the Church") was not that of the Church in the modern age.

Complex social and cultural factors were at play in the controversy. Ultimately, though, any historian attempting to make sense of the ideas and actions of Fr. Feeny and the members of the Center is confronted with the fact that they took theology seriously, and so also must the historian who hopes to understand them. My thesis in this

dissertation is that a uniquely explosive combination of theological developments, social flux, and intersecting personalities led to the eruptions at St. Benedict Center.

A comparison of associate degree nursing students' Kaplan Diagnostic Examination® scores to first-time NCLEX-RN outcomes



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KEYWORDS:

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(NCSBN);
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Standardized testing;
First-time NCLEX-RN
outcomes

Abstract

For nursing programs and their students, it is important that the associate degree nursing graduates have first-time National Council Licensure Examination for Registered Nurses (NCLEX-RN) success. This study examined standardized Kaplan® diagnostic examination scores for senior nursing students to first-time NCLEX-RN outcomes. It was found that the examination score of the Kaplan diagnostic examination® had a significant relationship to NCLEX-RN outcomes.

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1. Introduction

1.1. Background of Problem

The National Council State Boards of Nursing (NCSBN) is responsible for ensuring public protection for safe entry-level nursing through licensure. This organization is nursing's gateway and is responsible for writing, updating, and editing the National Council Licensure Examination for Registered Nurse (NCLEX-RN). The NCSBN's purpose is to "provide an organization through which boards of nursing act and council together on matters of common interest and concern affecting the public health, safety and welfare including the development of licensing in nursing" (NCSBN, 2012). In 1989, the NCSBN adopted a motion that required

the NCSBN Board of Directors to evaluate the passing standard for NCLEX-RN every 3 years, ensuring minimal competence for entry-level registered nurses (RNs). These increases occurred in 1998, 2004, 2007, and 2010 (Jones & Bremner, 2008; McGahee, Gramling, & Reid, 2010). These increases in passing standards were implemented to protect the public and prevent unqualified candidates from practicing nursing (NCSBN, 2012). With the implementation of these changes in the NCLEX-RN, nursing programs typically experienced a drop in their first-time NCLEX-RN pass rate the year the changes were implemented (National Council of State Boards of Nursing, 2013). The NCLEX-RN pass rate for a nursing program is published, and prospective students and the public correlate the pass rate with the quality of the nursing program (Pennington & Spurlock, 2010; Giddens, 2009). Therefore, nursing programs' pass rates are an important aspect of measuring the nursing programs' effectiveness and worth (DiBartolo & Seldomridge, 2005;

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Norton et al., 2006). With the NCLEX-RN pass rate decreasing with each increase in the NCLEX-RN passing standard (NCSBN, 2012), the need for nursing programs to prepare graduates for first-time success on the NCLEX-RN is even more challenging. One measure many nursing programs across the country have implemented is the usage of standardized exit testing to determine whether or not students are prepared for the NCLEX-RN.

1.2. Purpose of the Study

The purpose of this study was to compare and contrast the Kaplan diagnostic examination® scores earned by senior associate degree nursing students to NCLEX-RN outcomes at one nursing program in the northeast. This study focused on the Kaplan diagnostic examination® because nursing research related to the Kaplan diagnostic examination® and NCLEX-RN outcomes was lacking in literature. The literature does find that the use of standardized exit testing assists in preparing students for the NCLEX-RN because these exit tests are computerized and simulate the NCLEX-RN (Davenport, 2007; Firth, Sewell, & Clark, 2006).

1.3. Research Question

The research question asked related to the Kaplan diagnostic examination® and NCLEX-RN outcomes was, "What is the comparison of students' scores on the standardized Kaplan diagnostic examination® to NCLEX-RN outcomes on the first attempt?"

2. Literature Review

The usage of standardized exit testing has become common practice for many nursing programs across the country in determining NCLEX-RN outcomes and preparing graduates for the NCLEX-RN (Adamson & Britt, 2009; Alameida et al., 2011; Bondmass, Moonie, & Kowalski, 2008; McGahee et al., 2010). There are various companies that provide standardized exit tests to prepare graduates for the NCLEX-RN. These programs provide exit testing and integrated components such as practice questions, tests, and proctored tests that can begin in the students' first semester. It should be noted that these tests are not designed to predict the likelihood of NCLEX-RN failure (Harding, 2010; Jones & Bremner, 2008; Spurlock & Hunt, 2008).

The Health Education Systems Incorporated® (HESI®) exit examination is the most commonly referenced and researched exit test identified in the literature in relation to NCLEX-RN success (Adamson & Britt, 2009; Lavandera et al., 2011; Nibert, Young, & Adamson, 2002; Young & Wilson, 2012). The HESI® exit examination is a 150 multiple-choice, comprehensive, computerized nursing exit examination with multiple versions available. It is typically administered in the

last semester or quarter of a nursing curriculum, and has been validated by multiple research studies with multiple versions of the HESI® exit examination. Research of the HESI® exit examination has demonstrated a predictive accuracy above 90% (Young & Wilson, 2012). The HESI® predictability model is used to calculate all the exit examination scores (Nibert et al., 2002). The reliability of the HESI® exit examination is carried out by conduction of an item analysis of each examination by HESI® with an estimated reliability coefficients ranging from 0.94 to 0.96 (Morrison, Adamson, Nibert, & Hsia, 2004). Validity of the HESI® exit examination is ongoing but has been confirmed through construct validity, content validity, and criterion-related validity (Morrison, Adamson, Nibert & Hsia, 2004).

A second exit test is the Assessment Technologies Institute® (ATI®) comprehensive predictor, previously known as *ERI*, which is a 180-item multiple-choice test. The comprehensive predictor has multiple versions and is recommended to be administered near the end of the nursing program with a reliability of 0.79% for both versions of the proctored assessment (ATI, 2009). Validity of the ATI comprehensive predictor® has been determined through content validity, and a point biserial correlation is used to calculate a students' total test score (ATI, 2009). There have been some studies in the literature to examine students' ATI scores to NCLEX-RN outcomes (Alameida et al., 2011; Bondmass et al., 2008).

The Kaplan diagnostic examination® is a 180-item computerized examination with multiple versions that simulates the NCLEX-RN for students. The Kaplan diagnostic examination® scores are reported in percentiles, and Kaplan® predicts the student's first-time success on NCLEX-RN by using logistic regression (Saunders, 2011). Kaplan® (2011) found that their diagnostic examination accurately predicted success rate at 93.1%, and scores of 70% on the diagnostic exit examination had a 95.5% probability of passing the NCLEX-RN. Validity of the Kaplan diagnostic examination® was not located in the literature. The review of empirical literature on standardized exit testing is vast, but there is a gap in literature as it relates to the Kaplan diagnostic examination®. Therefore, this research was carried out to compare the Kaplan diagnostic examination® scores to first-time NCLEX-RN outcomes at one associate degree nursing program.

3. Methods

A pilot research study was carried out to collect data to add to the body of knowledge in the literature on standardized testing and NCLEX-RN outcomes. The independent variable of the Kaplan diagnostic examination® was compared with the dependent variable of NCLEX-RN outcome on first attempt.

3.1. Design

A descriptive, retrospective, comparative design was used for this pilot research study. A between-subject comparative design was utilized that involved four semesters of senior

associate degree nursing students. The dependent variable was measured by first-time NCLEX-RN outcomes. The independent variable of the Kaplan diagnostic examination® scores was based on the students raw percentage scores.

3.2. Sample

The randomized sample was from an urban private college in the northeast. This nursing program was approved by the Massachusetts State Board of Nursing and accredited by the National League of Nursing. The nursing program admits students in the fall and spring semesters. A retrospective randomized sample consisted of 220 senior nursing students from four semesters in the periods of 2010 and 2011, resulting in a final sample size of 140. The rationale for this number is based on recommended sample sizes for populations in Patten (2007) and data availability. An unordered list utilizing systematic sampling was used to select each of the students in the four semesters. Each semester contained a randomized sample of 35 senior nursing students. Because the researcher was a faculty member teaching some of the nursing students, randomization was carried out to reduce any potential bias. The criteria for inclusion were senior nursing students who took the Kaplan diagnostic examination®, students who achieved a passing grade of 78% or higher for their senior medical-surgical course grade, and students who took the NCLEX-RN for the first time. The Kaplan diagnostic examination® scores were retrieved from the Kaplan® on-line database because Kaplan® is an on-line program and the NCSBN quarterly reports provided first-time NCLEX-RN outcomes. Institute research board approval was obtained from the college where the research took place.

3.3. Kaplan Diagnostic Examination®

The Kaplan® program utilized at this college was integrated into the nursing curriculum from the first nursing course until graduation for all nursing students. The Kaplan® program included an NCLEX-RN review course after course completion and a variety of teaching tools, such as standardized proctored tests at the end of each nursing courses, multiple assigned focus tests, and assignment of multiple practice questions. In the final semester, students had access to the Kaplan® NCLEX-RN review program, which had a variety of on-line tutorials available to the senior nursing students. These tutorials contained a strategy seminar, test-taking workshop, review of content, review of question, video clips, and decision tree. The Kaplan diagnostic examination® was a component of this nursing program and was administered in the final nursing course, 2 weeks before administration of the final examination. Students prepared for this exit examination by completing all components of the NCLEX-RN review program that was assigned by faculty on a weekly basis. The Kaplan diagnostic examination® was weighted as a test grade during the first

three semesters of this study, and during Semester 4, students were awarded extra points based on their raw percentage score on this examination. This nursing program set 65% as the benchmark for mastery for the Kaplan diagnostic examination® because Kaplan's® research correlated a score of 65% to a 94.8% probability of passing the NCLEX-RN (Kaplan, 2011).

3.4. Data Analysis

The data were analyzed using Statistical Package for Social Sciences 20. Descriptive statistics of frequency, mean, and standard deviation were used to compare Kaplan diagnostic examination® scores of each of the four semesters to NCLEX-RN outcomes. A *t* test was done to compare the group mean Kaplan diagnostic examination® scores from each of the four semesters and the four semesters combined to NCLEX-RN pass/fail. A *t* test was utilized because this test is recommended when examining the group differences when a variable is considered interval level of measurement (Burns & Grove, 2011).

4. Results

4.1. NCLEX-RN Outcome

For the dependent variable of first-time NCLEX-RN outcome, 120 (85.7%) students passed NCLEX-RN on the first attempt, and 20 (14.3%) failed. In comparing the pass and fail rate each semester, it was comparable (Table 1).

4.2. Kaplan Diagnostic Examination® Scores

In analyzing the independent variable of the Kaplan diagnostic examination®, a mean of 63.53 resulted for the 140 students. Scores for the Kaplan diagnostic examination® ranged from 40% to 78%, with the most frequent grades recorded as 63% (*n* = 13) and 66% (*n* = 13) followed by 61% (*n* = 12). A total of 60 grades were above 65%, at which Kaplan® predicts the student has a 94.8% probability of passing NCLEX-RN (Kaplan, 2011).

4.2.1. Kaplan Diagnostic Examination® Scores Total Sample Compared with NCLEX-RN Outcomes

In comparing students who passed the NCLEX-RN to students who failed the NCLEX-RN, students who passed

Table 1 NCLEX-RN pass and fail frequency and percentage

	Pass	Fail
	# %	# %
Semester 1 <i>n</i> = 35	30 (85.7)	5 (14.3)
Semester 2 <i>n</i> = 35	31 (88.6)	4 (11.4)
Semester 3 <i>n</i> = 35	30 (85.7)	5 (14.3)
Semester 4 <i>n</i> = 35	29 (82.9)	6 (17.1)
Total sample <i>N</i> = 140	120 (85.7)	20 (14.3)

Table 2 Kaplan diagnostic examination mean according to NCLEX-RN pass/fail

	NCLEX-RN	N	Mean
Kaplan diagnostic Examination	Pass	120	64.47
	Fail	20	57.90

the NCLEX-RN on the first-attempt ($n = 120$) had a mean of 64.45 on the Kaplan diagnostic examination®, whereas students who failed the NCLEX-RN ($n = 20$) had a mean of 57.90. The mean score for students who passed was close to the 65% benchmark set by the nursing program. When comparing the pass to the fail group, there was a mean difference of 6.55% between the two groups (Table 2). The differences in the means for the Kaplan diagnostic examination® was analyzed using an independent t test. The Kaplan diagnostic examination® mean of the group who passed the NCLEX-RN first time (64.47) to students who failed NCLEX-RN (57.90) revealed a statistical difference ($P = .00$).

4.2.2. Kaplan Diagnostic Examination® Scores Each Semester Compared with NCLEX-RN Outcomes

The Kaplan diagnostic examination® mean was then analyzed within each of the four semesters. In Semester 1, the mean for the pass and fail groups were comparable, with the pass group having a higher mean by 1.53% than the fail group. For Semester 2, a variation in the mean pass and fail scores was noted with the pass group having a higher mean by 9.2% than the fail group. In Semester 3, the group who passed NCLEX-RN had a higher mean Kaplan diagnostic examination® score by 6% compared with the group who failed the NCLEX-RN. Semester 4 had the greatest difference in mean scores between the pass and fail groups, with the pass group having 9.23% higher than the mean of those who failed (Table 3). The differences in the means for Kaplan diagnostic examination® were analyzed using an independent t test that found the Kaplan diagnostic examination® to be significant ($P = .00$) to NCLEX-RN outcomes for Semesters 2, 3, and 4. Semester 1 was not significant ($P = .55$) because the group mean of the Kaplan

Table 3 Kaplan mean for semester according to NCLEX-RN pass/fail

	NCLEX RN	N	Mean
Semester 1	Pass	30	66.53
	Fail	5	65.00
Semester 2	Pass	31	63.20
	Fail	4	54.00
Semester 3	Pass	30	66.20
	Fail	5	60.20
Semester 4	Pass	29	61.90
	Fail	6	52.67

Table 4 Independent t test for each semester for Kaplan diagnostic examination

	P
Semester 1	.55
Semester 2	.00*
Semester 3	.00*
Semester 4	.00*

* $P < .05$.

diagnostic examination® scores was comparable to the pass (66.53) and fail (65.00) group in this semester (Table 4).

4.2.3. Kaplan Diagnostic Examination® Scores of Students Who Failed NCLEX-RN

The group of students who failed, $n = 20$, NCLEX-RN were then analyzed using descriptive statistics. The majority of students who failed NCLEX-RN, $n = 17$ (85%), scored below the 65% benchmark set by the nursing program on the Kaplan diagnostic examination®. There were three exceptions; one student scored 65%, and two students scored 69% on the Kaplan diagnostic examination® with an average mean of 57.90 for these three students.

4.3. Discussion of Findings

This study found the Kaplan diagnostic examination® scores to have a significant relationship ($P = .00$) with NCLEX-RN outcome. The mean Kaplan diagnostic examination® scores were considerably higher for those who passed the NCLEX-RN than those who failed. These results found that students with higher Kaplan diagnostic examination® scores were more likely to pass the NCLEX-RN on their first attempt and that students with low Kaplan diagnostic examination® scores were more likely to fail NCLEX-RN on first attempt. This finding is also supported in the literature because numerous studies have found standardized exit examination scores to be significantly related to NCLEX-RN outcomes (Adamson & Britt, 2009; Alameida et al., 2011; Bondmass et al., 2008; Crow, Handley, Morrison, & Shelton, 2004; Higgins, 2005; Lavandera et al., 2011; McGahee et al., 2010; Nibert et al., 2002; Sayles, Shelton, & Powell, 2003). Because this was one of the first studies to compare Kaplan diagnostic examination® scores to NCLEX-RN outcomes, the results from this study added to the body of knowledge in the area of standardized exit testing.

5. Limitations

This was a pilot retrospective study at a single associate degree nursing program; therefore, the results may not be reflective of other Associate Degree programs because content and different teaching methodologies exist throughout various associate degree programs. These results are related to an

associate degree nursing program and, therefore, cannot be generalized to diploma or baccalaureate programs. The literature outlines that many factors play a role in first-time NCLEX-RN outcome and that the focus on this study was a single variable that did not take into account any other variables that may have affected the first-time NCLEX-RN outcomes.

6. Recommendations

Recent NCSBN RN licensure statistics shows that associate degree students taking the NCLEX-RN outnumber baccalaureate students (NCSBN, 2012) and research focusing on associate degree outcomes related to standardized exit testing is limited in the literature. Passing the NCLEX-RN on the first attempt is important for both the student and the nursing program. First-time NCLEX-RN pass rates are directly tied to accreditation and viability of the nursing program. Thus, it is of upmost importance that nursing programs prepare students to succeed on the NCLEX-RN. The importance of identifying students who may benefit from remediation prior to taking the NCLEX-RN is essential. In this study, the Kaplan diagnostic examination® score was significant to first-time NCLEX-RN outcomes. Many studies have been conducted using a convenience sample of baccalaureate nursing students to examine the relationship of standardized exit testing to NCLEX-RN outcomes. Previous research done on the Kaplan diagnostic examination® was limited and was carried out by Kaplan®. This is one of the first studies to compare Kaplan diagnostic examination® scores for associate degree students using a randomized sample. The findings from this study is consistent with previous research in examining the relationship between standardized exit testing and NCLEX-RN outcomes. This study found that the Kaplan diagnostic examination® had a significant interaction with NCLEX-RN performance because students who passed the NCLEX-RN had a mean score of 64.47%, which is close to the 65% benchmark set by this nursing program, compared with students who failed who had a mean score of 57.90%. Students at this one nursing program who scored less than 60% on the Kaplan diagnostic examination® were encouraged to meet with the faculty member who was the "Kaplan coach" to review their areas of weaknesses and to set up a remediation plan in order to better prepare them for NCLEX-RN success. The results of this study highlights the importance these exit scores have in relation to NCLEX-RN outcomes and emphasize the need for faculty and students to work together in understanding their results. Continued research is recommended to evaluate effectiveness of preparation and remediation practices as related to NCLEX-RN outcomes.

7. Summary

As the RN licensure examination changes every 3 years, the need for nursing programs and faculty to implement strategies to best prepare student success on the NCLEX-RN

needs to be a priority. The variables that affect NCLEX-RN outcomes have been studied for many years in the literature. Factors that influence NCLEX-RN success vary from student to student and program to program, so it is difficult to study all of the influencing variables. It becomes the decision of nursing faculty to determine which variables related to NCLEX-RN outcomes are important to research. This study adds to the literature about standardized exit testing because this is one common variable that occurs in many associate degree programs. Standardized exit testing is one common variable that can assist in preparing students for NCLEX-RN in associate degree programs.

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A Brief Overview of History Management and Holistic Care of Sickle Cell Disease -

A Summary of the Disease

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Author Note

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Abstract

Sickle cell anemia (SCD) is a disease that has been around for many years. Many people of African descent are unfortunately born with it, and suffer an unspeakable amount from the disease. While we know little about the cure that is in place, even so, it doesn't seem in reach for most, considering the cost amongst other factors. However, there is hope on the horizon. The people of Nigeria may have discovered a natural holistic route for treatment of SCD that will be available and FDA approved in the United States! As you will see this can be the hope and answering of the prayers of all who have been involved, diagnosed or cared for a loved one with this disease. In understanding Sickle Cell Disease it will clarify the struggle that countless children, men and women have to endure and why it is so important to be aware of the life outside of what you have come to commonly know.

Keywords: sickle cell disease, history, traditional medication, alternative medication, African descent

What is SCD?

The term sickle cell disease (SCD) describes a group of inherited red blood cell disorders. People with SCD have abnormal hemoglobin, called hemoglobin S or sickle hemoglobin, in their red blood cells (National Institutes of Health, 2015). Normal red blood cells are shaped like discs or donuts with the centers partly scooped out. They are soft and flexible so they can easily move through very small blood vessels and deliver oxygen throughout a person's body (Miller, 2015). However, sickle-shaped cells are not flexible and can stick to vessel walls, causing a blockage that slows or stops the flow of blood. When this happens, oxygen can't reach nearby tissues. The lack of tissue oxygen can cause attacks of sudden, severe pain, called "pain crisis" (National Institutes of Health, 2015). Pain crises can be brief or last hours, days, or even weeks (Miller, 2015). These pain attacks can occur without warning, leaving many patients debilitated and sometimes requiring admittance to the closest available hospital (National Institutes of Health, 2015).

Fortunately, early detection (as early as 5 to 6 months of age) can save many people from the excruciating pain they will endure and prompt them to get the proper treatment before the pain crisis begins. Some of the signs that might occur are: painful swelling of the hands and feet, known as *dactylitis*; fatigue or fussiness from anemia; and a yellowish color of the skin, known as *jaundice*; or whites of the eyes, known as *icteris* (National Institutes of Health, 2015). Subsequent to these early symptoms, tests would be run to confirm or refute this hypothesis. A blood test can check for hemoglobin S — the defective form of hemoglobin that underlies sickle cell anemia. In adults, a blood sample is drawn from a vein in the arm. In young children and babies, the blood sample is usually collected from a finger or heel (Mayo Clinic Staff, 2014). If these investigations indeed test positive for the presence of hemoglobin S, further management of the disease will begin.

Who Does It Affect The Most?

It has been found that the majority of the population that sickle cell anemia affects are those of African descent. However, this is not the only demographic that suffers from this affliction. It is estimated that: SCD affects 90,000 to 100,000 Americans. SCD occurs among about 1 out of every 500 Black or African-American births. SCD occurs among about 1 out of every 36,000 Hispanic-American births. SCT (Sickle cell trait) occurs among about 1 in 12 Blacks or African Americans (Sickle Cell Disease, 2015). Further research has revealed that Caucasians in Greece, Sicily, Turkey, and their offspring around the world suffer from sickle cell anaemia [sic]. In fact, the highest incidences of the sickle cell gene (S, for short) are not found in Africa at all; they are in India and Saudi Arabia (Konotey-Ahulu, 2015).

What is the history of Sickle Cell Disease?

On the 15th of November, 1910, Dr. James Herrick made the first official description in published literature of sickle cell disease. The cardiologist had a young patient, Walter Clement Noel, from the Caribbean island of Grenada, with the disease under his care. He displayed symptoms of what we now refer to as acute chest syndrome, a common complication of sickle cell disease (Smith, 2015). Shortly after, in 1911, a female patient, age 25 years, was described with symptoms of sickle cell disease. She had been in medical care for some years but had previously been diagnosed with a form of pernicious anemia with unusual characteristics (Smith, 2015). The third recorded case was that of a 21-year-old female who once again showed the blood film that was indicative of sickle cell disease (Smith, 2015). Lastly, in 1915, a 21-year-old male patient was the fourth case of sickle cell disease in published literature, and the first case employing that the terminology of "sickle cell anaemia [sic], " (Smith, 2015). In all of these cases each patient exhibited a blood film that demonstrated the form of sickle cell hemoglobin cells.

However, with the 1915 patient, it was noted that while there were no abnormalities evident in the fresh blood sample, some abnormal cells were evident after a few days. This became

the initial crude test of sickle cell disease, the first time the disease as an inherited condition had been suggested (Smith, 2015).

In what is known as the consolidation phase this is the period that terminology about the disease developed, including the “active” and “latent” forms of the disease, which were later clarified to be heterozygous and homozygous inheritance (Smith, 2015). At this time, some association between sickle cell trait and increased resistance against falciparum malaria was also observed (Smith, 2015). Researchers found that the sickle cell gene is especially prevalent in areas of Africa hard-hit by malaria (Nagel, 2001). It turns out that, in these areas, HbS hemoglobin S) carriers have been naturally selected, because the trait confers some resistance to malaria. Their red blood cells, containing some abnormal hemoglobin, tend to sickle when they are infected by the malaria parasite. Those infected cells flow through the spleen, which culls them out because of their sickle shape -- and the parasite is eliminated along with them (Nagel, 2001). In 1949, for the first time, electrophoresis showed that sickle hemoglobin [*sic*] moved at a different rate to normal hemoglobin [*sic*], suggesting a molecular change in the abnormal cell (Smith, 2015). When hemoglobin [*sic*] electrophoresis became widely available in 1954, opportunities to differentiate between different forms of sickle cell disease became possible. This led to sub-classification of the disease, as we refer to them today (Smith, 2015).

In the current awareness phase, research studies have concluded that the early life phase of between six months to one year was most likely to lead to serious events, which could be fatal or severely impact the quality of life. This knowledge led to the rise of infant screening to identify newborns who were at risk, a measure that has proved to be of great benefit (Smith, 2015). Although there is a sure means of SCD early detection, which saves many lives from the uncertainty of the resulting complications, we cannot say the same for a cure.

What Are The Traditional Treatments of SCD?

As mentioned previously there are few cures for sickle cell anemia. In fact, currently, the only known cure for sickle cell disease is bone marrow or stem cell transplant (Children's Hospital at Vanderbilt, 2012). A bone marrow transplant is a procedure that takes healthy bone marrow cells from a person who does not have sickle cell disease (the donor) and gives them to the person who has sickle cell disease (the recipient) to replace the bone marrow that is providing sickle cells (Children's Hospital at Vanderbilt, 2012). Bone marrow transplantation is a major undertaking and can have serious complications. These include: anemia; bleeding in the lungs, intestines, brain, and other areas of the body; cataracts; clotting in the small veins of the liver; damage to the kidneys; liver, lungs, and heart. Also, delayed growth in children who receive a bone marrow transplant, early menopause; graft failure, which means that the new cells do not settle into the body and start producing stem cells; as well as Graft-versus-host-disease (GVHD), a condition in which the donor cells attack your own body. Once more, complications may include infections, which can be very serious; inflammation and soreness in the mouth, throat, esophagus, and stomach, called *mucositis*; pain, stomach problems, including diarrhea, nausea, and vomiting (National Institutes of Health, 2015). Furthermore, for the transplant to work, the bone marrow must come from a donor who is a close match, usually a healthy sibling who has the same set of parents as the child with sickle cell disease (Children's Hospital at Vanderbilt, 2012). Often this might not be an option for, say, children who are adopted or who do not have any biologically living parents. Therefore, another option would be to undertake a process of managing the disease in making the patient comfortable when pain crises occur and to prevent complications.

The patient would see their health care provider regularly (meaning every 3-12 months), depending on the person's age (National Institutes of Health, 2015). Here the provider would examine the patient, provide medicines and immunizations, perform tests, as well as educate families about the disease and what symptoms to monitor (National Institutes of Health, 2015). Special attention would be paid to the proper functioning of the spleen. In addition, people with SCD are more likely to acquire severe infections. Therefore, they need to take antibiotics on a

regular basis. In children with SCD, taking penicillin twice daily has been shown to reduce the chance of having a severe infection caused by the pneumococcus bacteria. Infants need to take liquid penicillin (National Institutes of Health, 2015). Older children and adults (if continued use is permitted) can take tablets (National Institutes of Health, 2015). Additional vaccines as supplements to those administered routinely are: Pneumococcus, Influenza and Meningococcus (National Institutes of Health, 2015).

Some of the tests administered to monitor a patient's health and lower the chances of the previously mentioned complications are: height, weight, blood pressure, oxygen saturation, as well as blood and urine testing, Transcranial Doppler (TCD) Ultrasound Screening (This study can detect whether a child is at higher risk for stroke), eye examinations, pulmonary hypertension and cognitive screening (National Institutes of Health, 2015).

If, indeed, a pain crisis does manage to evade detection, the doctor would prescribe certain pain relievers, based on the category of the pain. For acute pain they would prescribe a basic Nonsteroidal anti-inflammatory drug (NSAID), such as Ibuprofen. However, as the pain worsens, the physician will increase the strength and potency of the pain reliever and prescribe various remedies: duloxetine, gabapentin, amitriptyline, and strong pain medicines such as opiates (a practice now under increasing scrutiny due to the current nationwide opioid epidemic). Unfortunately, for some people with SCD, complications do occur and this is where a very popular drug called Hydroxyurea is prescribed. Hydroxyurea is an oral medicine that has been shown to reduce or prevent several SCD complications (National Institutes of Health, 2015). It is commonly administered to children and adults with hemoglobin SS or S β 0 thalassemia, who have frequent painful episodes, recurrent chest crises, or severe anemia (National Institutes of Health, 2015).

The last option within traditional maintenance is Red Blood Cell Transfusions. A transfusion helps to raise the number of red blood cells and provides normal red blood cells that are more flexible than red blood cells with sickle hemoglobin. These cells live longer in the circulatory system, red blood cell transfusions decrease vaso-occlusion (blockage in the blood vessel) and

improve oxygen delivery to the tissues and organs (National Institutes of Health, 2015). Given all the various ways that a physician can potentially cure or make a patient with SCD comfortable, many choose to employ the holistic route and use traditional herbal treatments that have been around for eons to remedy the complications and pain.

What is known of the Holistic Management of SCD?

Here we can first take a look at one of the areas where SCD is prevalent, Africa, specifically Nigeria, West Africa. Patients in West Africa where sickle cell anemia (SCA) is endemic have for ages been treated with natural products, especially herbs, as is still the case in rural communities (Ameh, Tarfa, & Ebeshi, 2012). In Nigeria, the indigenous are not aware of any specific name for sickle cell disorder, but we know that the condition is common and is classed among diseases believed to be caused by evil spirits or misconduct (Ameh, Tarfa, & Ebeshi, 2012). There is an abundance of herbal treatments for SCD but here we will only mention the most popular. First, we take a look at Vanilloids, specifically capsaicin. This herb has the ability to cause pain (i.e., the burning sensation) which, ironically, makes this botanical useful in alleviating pain. Moreover, it has anti-sickling properties (Ameh, Tarfa, & Ebeshi, 2012). A small jolt of capsaicin excites the nervous system into producing endorphins, which promote a pleasant sense of well-being. The endorphin lift makes spicy foods mildly addictive (and for some, an obsession) (Ameh, Tarfa, & Ebeshi, 2012). The second herbal, better known as cannabis or marijuana, is classified as a cannabinoid. Two receptors within our body, subtypes—CB1 (expressed mainly in the CNS, lungs, liver, and kidneys) and CB2 (expressed in the immune system, hematopoietic cells, and peripheral nerve terminals where they function in pain control)—are known. All these tissues are involved in SCA pain crisis; this is where cannabinoids come into play and relieve or diminish pain symptoms according to empirical evidence (Ameh, Tarfa, & Ebeshi, 2012).

Also, in Nigeria, there has been an abundance of research focused on a group of herbs renowned throughout Nigeria. It is an herbal combination extract called Niprisan (Adams, 2015).

After examining the evidence, researchers from Nigeria's National Institute for Pharmaceutical Research and Development (NIPRD) have concluded that several herbs, and one particular combination of herbal extracts, provide evidence of being potentially effective treatments for sickle cell anemia (Adams, 2015). Based on a traditional African healing remedy for treating sickle cell-like symptoms, the primary constituents of Niprisan (or Nicosan) are derived from extracts of the following plants: Piper guineense seed, the West African pepper or Guinea pepper, eterocarpus osum stem, eugenia caryophyllus, sorghum bicolor (Adams, 2015). In a Phase III clinical trial, among the 30 sickle cell patients given the herbal formula, 73% had no sickle cell crisis during the twelve-month testing period, while the remainder of the group – 27% – had fewer and less severe sickle cell crises (Adams, 2015). In another trial, which included 82 patients, Nicosan was found again to be effective in significantly reducing sickle-cell crises among those given the herbal combination (Adams, 2015).

With That Said....

Sickle cell anemia is a debilitating disease. Truly, I take my hat off to the parents who have maintained their composure and remained strong, not only for their family, but for themselves as well. As someone who also has the sickle cell anemia trait present in my family it is equally important for me to know about this disease. To fully understand this disease helps not only me but my family to become more knowledgeable about our health, history and ethnicity. Fortunately, as mentioned before, there is a cure for SCD. Shockingly, many incur excessive costs to have a bone marrow transplant; determined expenses, meanwhile, will vary based on the patient's insurance coverage. Unfortunately, the total cost of a transplant is typically \$350,000-\$800,000, depending on whether the procedure is autologous (some of the patient's own marrow or stem cells are used), or allogeneic (i.e., meaning cells are harvested from a donor) (Cost Helper Health, 2015). Allogeneic transplants are associated with increased cost, because, among other factors,

donors will need to be tested, placed under general anesthesia and admitted to an operating room so that bone marrow can be collected (Cost Helper Health, 2015).

A 2011 report on the cost of organ and tissue transplant, for example, found an allogeneic bone marrow transplant typically cost \$805,400 total. The report estimates the total cost for an autologous transplant to be \$363,800 (Cost Helper Health, 2015). Even with insurance the remaining bill for this is just too expensive. Seeing that the majority demographic of SCD consists of people of African descent, this in itself constitutes a major barrier to treatment access. The median, yearly income for African Americans in 2010 was \$39,715, down from about \$44,000 in 2000. As a percentage of white median family income, blacks made 61 percent in 2010, down from 63.5 percent in 2000 (Economic Policy Institute, 2015). In 2011, 36 percent of blacks, including 38.1 percent of black women, were employed in low-wage jobs (earning poverty-level wages or less). Among the white labor force, 23.4 percent were employed in low-wage jobs (Economic Policy Institute, 2015). In 2010, the median wealth, or net worth, for black families was \$4,900, compared to median wealth for whites of \$97,000 (Economic Policy Institute, 2015). This does not include the unfathomable poverty percentages within Africa, where the disease is prevalent.

Thank God, humanity has found alternative treatments for SCD and options to keep patients diagnosed with SCD comfortable, hopeful and faithful for that day when a cure can be within everyone's reach. According to Dr. Deepak Chopra, we should keep in mind that:

Situations seem to happen to people, but in reality, they unfold from deeper karmic causes. The universe unfolds to itself, bringing to bear any cause that needs to be included. Don't take this process personally. The working out of cause and effect is eternal. You are part of this right rising and falling that never ends, and only by riding the wave can you ensure that the waves don't drown you. The ego takes everything personally, leaving no room for higher guidance or purpose. If you can, realize that a cosmic plan is unfolding and appreciate the incredibly woven tapestry for what it is, a design of unparalleled marvel. (Chopra, 2004, p. 137)

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Effects of Breast Cancer in Young Women

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EFFECTS OF BREAST CANCER IN YOUNG WOMEN

Abstract

Breast cancer is the leading cause of death in women aged 40 years and younger. Surprisingly, those who have breast cancer when they are younger tend to have a more severe prognosis and more negative long lasting effects. These young women experience many issues that older women with the same prognosis don't face, such as body image issues and fertility trouble. Because of the different struggles younger women face with breast cancer, they may choose different treatment options. It is important for these women to perform regular screenings on their own to try to catch the cancer at an early stage due to regular professional screenings not being available to them at a young age.

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Effects of Breast Cancer in Young Women

A diagnosis of breast cancer is devastating for anyone, especially younger women under the age of 40. Even though it is rare to be diagnosed with cancer under the age of 40, younger women often face a worse prognosis and higher death rate compared to older women with breast cancer (Buchanan, Roland, Rodriguez, Miller, & Fairley, 2013). Even though there have been many medical advances in breast cancer treatment, approximately 40,000 women succumb to this disease each year (Buchanan et al., 2013). These women face special issues and risks due to their young age. Body image, treatment and fertility complications are just a few issues young women deal with while battling cancer.

Discussion

Fertility Issues

For young women who are diagnosed with breast cancer, fertility issues could be a great concern for them and could play a major factor in the kind of treatment options they choose (Ruddy et al., 2014). Cancer treatments can greatly damage fertility in women whether by chemotherapy or endocrine therapy by direct gonadotoxicity or delays to the aging of ovaries (Ruddy et al., 2014). Chemotherapy can also cause early menopause, even for those who are still menstruating (Ruddy et al., 2014). To better understand the concerns young women have about fertility issues, newly diagnosed women under the age of 40 who have early stage breast cancer were surveyed about their experience with fertility concerns (Ruddy et al., 2014). Of the 724 women that answered the survey, two hundred thirty women wished to have future biological children before their diagnosis and 160 women wished to have biological children sometime in the future (Ruddy et al., 2014). These women who wished for future biological children chose to avoid or go with certain treatment options (Ruddy et al., 2014). Some chose not to receive some types of chemotherapies and endocrine therapies and some chose to have mastectomies due to their concerns (Ruddy et al., 2014). Some women even went a step further and went through with embryo cryopreservation to try to lessen the chance of infertility (Ruddy et al., 2014). For those who do not have male partners, oocyte cryopreservation is also an option if they choose not to use a sperm donor, but would like biological children in the future (Ruddy et al., 2014). A technique called GnRH-a is an injection that is administered during chemotherapy that is used to protect ovarian function during treatment (Ruddy et al., 2014). This is less invasive and carries no increased risk of tumor growth due to elevated estrogen levels (Ruddy et al., 2014). Not surprisingly, those who had not started having children yet were more concerned about infertility than were older women who had already completed their childbearing years (Ruddy et al., 2014). One study showed that women would like to be more informed about the risk of infertility and the options they have to decrease this risk (Ruddy et al., 2014). Even though some physicians believe that pregnancies could cause a relapse in cancer, most evidence suggests that women who get pregnant after breast cancer could have a better prognosis for the future (Ruddy et al., 2014). This is due to something they call the healthy mother effect, which suggests that healthy breast cancer survivors are more likely to get pregnant and carry to term than unhealthy survivors (Ruddy et al., 2014).

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Mastectomy and Breast-Conserving Therapy. Young women have many options for treatments, such as chemotherapy and radiation, but there are also the options of having a mastectomy and breast-conserving therapy (BCT). For those women with early stages of breast cancer, some choose to have a mastectomy, which consists of removing one or both breasts, or they may choose breast-conserving therapy (BCT), which consists of a lumpectomy and radiotherapy (Barton, 2015). A study showed that women who underwent BCT were more likely to have a tumor that was smaller and also a more positive effect on the lymph nodes than those who underwent a mastectomy (Barton, 2015). Those who had BCT had a higher survival rate of 85.9% compared to 83.5% in those who had a mastectomy (Barton, 2015). The only time having a mastectomy had a better survival rate is when patients aged 20-34 with stage IIB cancer underwent the surgery and these women had an increased overall survival rate (Barton, 2015). These findings are important because many young women diagnosed with breast cancer tend to go for the mastectomy over the BCT treatment option (Barton, 2015). A study showed that the rate of double mastectomies increased from 9% to 24% in women younger than 46 years old between 2003 and 2010, while the number of lumpectomies decreased (Barton, 2015). It was showed that most women preferred mastectomies over radiotherapy (RT) because of the daily commitment for 6 weeks for RT (Barton, 2015). Health care professionals express concern over the increase in younger women undergoing mastectomies because it doesn't give the patient a better chance of survival and it can lead to a weakened quality of life (Barton, 2015).

Body Image Issues. Those who are diagnosed with breast cancer when they are young tend to experience more body image issues than those who are older. Cancer treatment can certainly take its toll on the body and can make women more self-conscious about their looks. Certain factors can attribute to these worries such as the loss of a breast(s), scarring and changes in weight to name a few (Rosenberg et al., 2013). A study was performed on the physical and emotional side effects young women have during cancer treatment (Rosenberg et al., 2013). Out of the women who participated in the study, who had an average age of 37, most of them were receiving chemotherapy and others had either endocrine therapy, mastectomy and reconstructive surgery or a lumpectomy (Rosenberg et al., 2013). Out of these treatment options, those who underwent a lumpectomy, which is less invasive, had the least amount of body image issues and those who had a mastectomy had the most issues (Rosenberg et al., 2013). Those who have reconstructive surgery were shown to have more body issues, at least in the short-term (Rosenberg et al., 2013). Chemotherapy also brought on symptoms such as fatigue that can lead to negative body image (Rosenberg et al., 2013). Lymphedema is a side effect of treatment than can negatively impact a women's image of her body and also have an emotional impact as well (Rosenberg et al., 2013). This trial found that exercising and participating in a weight training regimen helped women with their self-esteem and body image issues with an overall improvement on quality of life (Rosenberg et al., 2013). Women need to weigh each treatment option carefully and take into consideration each recovery time, such as between a mastectomy and a lumpectomy (Rosenberg et al., 2013).

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Conclusion

While it's not clear on how to prevent breast cancer all together, there are ways that young women can be educated in knowing what to look for to detect it and what can be done to help decrease the chances of getting cancer. By educating these women about breast cancer, many of the issues above may be avoidable if found early enough. Increasing awareness about these young women's issues is the first step in the process of educating about breast cancer.

Increase Attention to Unique Issues

Young women face unique issues that are associated with their diagnosis of breast cancer and it is important to educate the patient on treatment options and risks and to educate physicians on how to educate the patient. The Young & Strong study focuses on bringing to attention the above discussed issues in order to better inform the physician and patient (Greaney et al., 2015). Young women are concerned that their physicians are not fully informed of how to deal with the unique issues they face due to their young age, such as body issues and infertility, and that these issues need to be better addressed at appointments (Greaney et al., 2015). Young & Strong specifically focuses on young women with breast cancer and their health care providers (Greaney et al., 2015). The goal is to raise awareness about these young women's specific issues associated with breast cancer and how to better treat them and inform them (Greaney et al., 2015).

Diagnostic Delays. Detecting breast cancer at an early stage is crucial in terms of how aggressive of treatment is needed, quality of life and overall survival rate. Because breast cancer in young women is more likely to be more severe, early detection is important (Ruddy et al., 2014). In most women, their breast cancer was self-detected (Ruddy et al., 2014). A study that was performed showed that young women who waited more than three months to seek medical help after the first sign of a symptom were 12% less likely to have a five-year survival rate (Ruddy et al., 2014). Those who had longer delays had a worse prognosis (Ruddy et al., 2014). The average time between self-detecting cancer and seeking medical help was 16.5 days (Ruddy et al., 2014). It was found that those who were financially unstable were less likely to seek medical help right away due to the impending burden of the high cost of medical care (Ruddy et al., 2014). Luckily this study found that most women don't delay in seeking medical attention after the first symptom as that could lead to a higher stage of cancer (Ruddy et al., 2014).

Future Research/Awareness. Unfortunately, young women who are diagnosed with breast cancer face a more aggressive disease than older women (Buchanan et al., 2013). Mammograms are not routine for women under 40 years of age, which could help detect the cancer early, so it is up to these young women to detect it themselves through regular self-screenings (Buchanan et al., 2013). Young women face more long term side effects such as infertility and cardiac issues due to treatment (Buchanan et al., 2013). Participants in a study discussed certain factors that had "strong" evidence on contributing to the onset of breast cancer, such as family history, race and age (Buchanan et al., 2013). It was suggested that communication needed to be enhanced in order to better educate young women on being aware of their risk of developing breast cancer, such as knowing their family history (Buchanan et al., 2013).

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