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Electronic Brachytherapy Organ at Risk Dose: A Non-Inferiority Comparative Study between Iridium-192 and 50 Kilovoltage X-Ray Source Models at Steve Biko Academic Hospital

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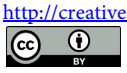

Abstract

Introduction: The use of the Xoft Axxent electronic Brachytherapy (eBx) system has become more common due to advantages, like lower doses to the Organs At Risk (OARs), than the traditionally used radioactive sources like Iridium-192 (Ir-192). Xoft's eBx uses a miniaturised X-ray tube instead of a radioactive source. At Steve Biko Academic Hospital, the EMBRACE-II protocol is followed when planning and treating gynaecological brachytherapy patients to ensure that the OARs such as bladder and rectum reach the compliance of the dose constraints. Studies have shown that Ir-192 source models adhered to these constraints. Hence, with eBx becoming more popular, it is vital to ensure that the new technology is not inferior to Ir-192 when comparing the OARs doses. **Materials and Methods**: The study considered ten cervical cancer patients, planned with the 50 kV eBx source model and retrospectively planned with an Ir-192 source model. The delineated Planning Target Volume (PTV) and OARs were kept identical between the models. The retrospective planning aimed to replicate the PTV D90% of the initial plan. The difference in doses (D2cc) to Organs At Risk (OAR) between the models was calculated and expressed as a percentage. Statistical significance was determined using a paired t-test with a 95% confidence level. **Results**: For the rectum, the mean D2cc was **2.52 ± 1.05 Gy** for eBx and **2.78 ± 1.16 Gy** for Ir-192. For the bladder, the mean D2cc was **4.27 ± 1.46 Gy** for eBx and **4.36 ± 1.24 Gy** for Ir-192. The average difference in planned doses (D2cc) for the rectum and bladder between two models was 5.31% for the rectum and 0.11% for the bladder. These results for rectum doses were rendered statistically significant, whereas bladder results were insignificant. In both cases, the Ir-192 model delivered the higher OARs

doses. **Conclusion**: No significant differences were found in bladder dose (D2cc) when comparing the two source models. The eBx model delivered on average 5.31% less rectum dose (D2cc). eBx proves to be non-inferior to Ir-192 for gynaecological brachytherapy treatments.

Subject Areas

Oncology

Keywords

High Dose Rate Brachytherapy, Electronic Brachytherapy, Iridium 192

1. Introduction

1.1. Background

Traditionally, Brachytherapy (BT) involves the clinical application of small encapsulated radioactive sources (γ or β emitters) placed in close proximity to the target volume for the treatment of malignant tumours or non-malignant lesions [1]. This treatment modality is typically used only if a more conformal radiation dose distribution is required and the tumour is more localized [2].

Brachytherapy is typically subdivided into four main ways. The classifications are represented according to the types of implants, the dose rate, the treatment duration and lastly according to the source loading. The most common types of implants are interstitial, intracavitary, intraluminal, intravascular, and surface moulds. The dose rate classifications are low dose rate (LDR, 0.4 - 2 Gy/hr), medium dose rate (MDR, 2 - 12 Gy/hr), and high dose rate (HDR, >12 Gy/hr) [3]. The treatment durations can either be temporary or permanent and lastly the source loading can either be preloading or afterloading [3]-[5].

A radiation oncology department can use brachytherapy treatments for range of cancer types and treatment sites, but at Steve Biko Academic Hospital (SBAH) it is mainly used for the treatment of gynaecological cancers like cervical and vaginal cancers. Brachytherapy is used as a supplemental "boost" treatment following External Beam Radiation Therapy (EBRT). This approach aims to achieve the dose targets outlined in the EMBRACE-II study protocol, which involves maximizing tumour dose while limiting the exposure to surrounding Organs At Risk (OARs) [6]. According to the classifications described in [3]-[5], the department makes use of a remote afterloader that delivers dose at a high dose rate. This means that a "radioactive" source is placed inside (intracavitary-cervix) the patient for a temporary time to deliver the required dose.

Traditionally, radioactive sources like Ir-192 or Co-60 are used to deliver the brachytherapy treatments to patients [7]. Radioactive sources come in various shapes, but typically, an Ir-192 source is attached to a steel dummy wire and is designed to be safely stored within the remote afterloader when not in use for

patient treatment. This wire can be programmed to move from the afterloader into the patient via transfer tubes and applicators to stop at set dwell positions for set dwell times. One of the major disadvantages of traditionally used radioactive sources is the fact that they are always "hot" or "on", which means that they are always emitting ionizing radiation until they have sufficiently decayed. This means that in the case of emergencies, where the radioactive source is stuck or fails to retract into the safe position in the afterloader, staff and the patient will be over-exposed.

A new modality, known as Electronic Brachytherapy (EB), promises increased staff and patient safety and is becoming more widely used [8] [9]. The Axxent Electronic Brachytherapy System (eBx), developed by Xoft Inc. in Fremont, CA [10], is among the widely utilized electronic brachytherapy devices. This system employs vaginal and cervical applicators, akin to the Ir-192 intracavitary approach, to administer the required dose. However, instead of relying on radioactive sources such as Ir-192 or Co-60, the Axxent System features a compact, water-cooled X-ray source operating at 50 kV. This source is programmed to activate at specific points within the applicators for predetermined intervals to deliver the intended dose. Electronic Brachytherapy (EB) through this system presents notable benefits. For instance, the low-energy output of the Xoft device (50 kV) allows treatments to be performed in rooms without specialized shielding, contrasting the significant bunker requirements of HDR brachytherapy [11]. Furthermore, its low radiation exposure rate permits medical staff to remain close to the patient during treatment, fostering a supportive and reassuring environment.

Even though this type of brachytherapy is different, the computerized treatment planning procedure remains the same as with radioactive sources. The Treatment Planning System (TPS) uses the American Association of Physicists in Medicine (AAPM) Task Group (TG) 43 formalism to calculate the dose distribution within the patient during the treatment planning process [12]. The user is just expected to enter the correct TG-43 parameters into the TPS and thereafter the dose calculation can be done [13]. Due to SBAH being the first institution in Africa to commission and treat patients with the Xoft Axxent eBx controller, it is important to ensure that this new modality is not inferior to previously used modalities such as Ir-192 remote afterloaders.

The manufacturer of the Xoft Axxent electronic Brachytherapy (eBx) system claims that it provides lower doses to the Organs At Risk (OARs), than the traditionally used radioactive sources like Ir-192 [10]. This study serves as a preliminary trial in the clinical setting at SBAH to prove that the eBx system is not inferior to the Ir-192 source model when comparing the OARs doses. The OARs in this study refer to the rectum and bladder. The study evaluated the doses to these organs by analysing the maximum dose to two cubic centimetres (D2cc) using the Dose Volume Histogram (DVH) statistics in the TPS.

The study seeks to prove that the eBx system delivers equal or lower dose to the OARs (according to the EMBRACE-II study protocol), as shown in the recom-

mendations made by the GEC-ESTRO II working group. Common side effects of brachytherapy, such as inflammation, scarring, ulcers, tissue death and abnormal connections between organs, typically occur in small areas surrounding the treatment applicators (tandem & ovoids), where high doses (>70 - 80 Gy, EBRT + BT) radiation are applied. In contrast, side effects affecting the entire organ, such as widespread inflammation and scarring, are more likely to occur when the entire organ receives moderate to high doses of radiation (60 - 70 Gy, EBRT+ BT) [14].

1.2. Literature Review

Preliminary studies have been done regarding the treatment of cervical cancer patients with electronic brachytherapy, especially the eBx system [15] [16]. One of these studies outlines the treatment planning process of patients being treated with electronic brachytherapy using the EMBRACE-II study protocol [17]. According to the EMBRACE-II study protocol the dosimetry requirements during planning are as follows. The D90 High Risk Clinical Target Volume (HR-CTV) Equivalent Dose in 2 Gy fractions (EQD_2) should be between 90 Gy and 95 Gy, with 85 Gy being the lower limit recommended by the protocol. The OAR doses (D2cc) are lower than 80 Gy ideally (with 90 Gy being the high limit) for the bladder and lower than 65 Gy ideally (with 75 Gy being the high limit) for the rectum [17]. It is worth noting that these dose values represent the combined EBRT and BT EQD_2 values. Lozares-Cordero *et al.* (2019) suggest that the first results of cervical cancer patient treatments using the eBx system are promising, as the system meets the EMBRACE-II study protocol limits. They further highlighted that the eBx system is a good alternative to traditional HDR sources like Ir-192 or Co-60 [15]. The authors also stated that the toxicity is very low for this modality. Another protocol that is followed during 3D image-guided brachytherapy is the GEC-ESTRO I and II recommendations [14] [18]. The planning aim dose statistics are consistent between GEC-ESTRO and EMBRACE-II. Morbit *et al.* (2015) planned treatments retrospectively with the eBx system and found that it conformed to the GEC-ESTRO recommendations. The authors also claimed that the eBx system can potentially replace more traditional treatments like either Ir-192 or Co-60 when using tandem and ovoids to treat cervical cancer patients.

Both studies by Lozares-Cordero *et al.* (2019) and Morbit *et al.* (2015) also compared the OARs doses to determine the feasibility of the eBx system in the clinical setting. The main difference between these two studies is that Lozares-Cordero *et al.* (2019) first treated the patients with the eBx system and then retrospectively planned the patients with an Ir-192 source model, whereas Morbit *et al.* (2015) treated patients with Ir-192 and planned retrospectively with the eBx source model and with Co-60 [15] [16]. Both studies show that the OARs doses were lower for eBx plans than for Ir-192 plans. Morbit *et al.* (2015) reported a statistically significant difference for the bladder D2cc (~25% lower for eBx) and not for the rectum, whereas Lozares-Cordero *et al.* (2019) reported a statistically significant difference for the rectum D2cc (~19% lower for eBx) and not for the bladder.

The apparent contradiction between these two studies highlighted that the results were planner-specific, indicating that the differences were largely dependent on the physicists who planned the patient treatments. The fact, however, that both studies reported overall lower OARs doses, is very promising. Morbit *et al.* (2015) concluded that the eBx system can potentially replace either Ir-192 or Co-60 in tandem and ovoid treatments. Their study showed that the eBx system provides either better sparing of the OARs compared to Ir-192 or Co-60 or at least similar sparing [16].

A study by Dickler *et al.* (2008) compared the dose statistics of the eBx system to those of an Ir-192 HDR system in the treatment of endometrial cancer. This study differs from the previously mentioned studies, in that the applicator used is different. It used a vaginal applicator that only has one channel whereas the other studies used tandem and ovoids (three channels). This was due to the type of cancer being treated and the desired location of dose in the patient. Dickler *et al.* (2008) retrospectively planned treatments of 11 patients (who were previously treated with Ir-192) using the eBx source model [19]. Their study reported that the mean bladder percentage of volume receiving 35% of the prescribed dose (%V35) was 47.7% for the Ir-192 method compared to 27.4% for the eBx method, while the mean bladder %V50 was 26.5% for Ir-192 versus 15.9% for eBx. It also claims that the mean rectal %V35 was 48.3% versus 28.3% and the mean rectal %V50 was 27.8% versus 17.0% for the Ir-192 and eBx methods, respectively. All four sets of differences were found to be statistically significant. It was concluded that the eBx system provided highly sparing effect on the bladder and rectum [19]. It is important to note that the study by Dickler *et al.* (2008) made use of different dose statistic values and methods than the other studies by Lozares-Cordero *et al.* (2019) and Morbit *et al.* (2015). The previous two studies used dose statistics, whereas the third study used volume statistics. The consensus of these studies that compare eBx and Ir-192 dosimetrically is that the eBx system provides a more conformal dose distribution. This means that the dose to the PTV/CTV is higher, while the dose to the OARs is lower.

2. Materials and Methods

2.1. Materials

The only materials that were used were the in-house TPS at SBAH and Microsoft Excel. The software that was used to initially plan and later re-plan patients was BrachyCare (Técnicas Radiofísicas, Zaragoza, Spain) version 1.1.0.3.

2.2. Research Design

This formal study was a comparative non-inferiority trial. The first ten cervical cancer brachytherapy patients that were planned and treated (with tandem and ovoids) using the eBx system (50 kV X-ray source model) were selected and re-planned using an Ir-192 source model. The treatment planning process was simulated retrospectively using the Ir-192 source model, but on the same TPS. Before

this Ir-192 source model could be used for the research, it had to first be imported into the BrachyCare TPS and commissioned to confirm the TG-43 parameters and validity of the model. There was no involvement of active patient in this study, as it solely used patient data (CT scan data and DVH statistics), making it, by nature a "monitoring" study. There was also no change in the patients' perceptual awareness, due to no active participation. This was an experimental study, where eBx dose statistics (OARs D2cc) were compared to the Ir-192 dose statistics, while keeping the dose to 90% of the planning target volume (PTV D90) constant between the two source model plans. The aim was to prove that the eBx OARs D2cc is lower than or the same as the Ir-192 OARs dose, and to make a conclusion about the target population (causal-predictive). Statistical analysis was used to draw a conclusion regarding the hypotheses. Since these ten patients were all re-planned at once, and statistical analysis was done afterwards, this was a cross-sectional study.

2.3. Sampling

2.3.1. Target Population

Patients who receive brachytherapy treatment for gynaecological cancers at Steve Biko Academic Hospital (SBAH) using tandem and ovoids.

2.3.2. Sample Size

The sample size was ten patients. These ten patients were the first patients to have received electronic brachytherapy treatments with the eBx system at SBAH. The advantage of such a small sample size meant that a preliminary analysis could be done without having to wait for a larger number of patients to be treated.

2.4. Data Collection

2.4.1. Collection Method

The first ten patients treated using eBx at Steve Biko Academic Hospital were retrospectively re-planned using an Ir-192 source model. Brachytherapy fractionation was individualised per patient, with dose per fraction adjusted to meet cumulative EQD2 targets. As this study was retrospective, a single fixed prescription dose was not applied across all patients. Brachytherapy was typically delivered in 3 - 4 fractions of 6.5 - 7.0 Gy per fraction, with the final fractionation selected to achieve a cumulative HR-CTV D90 EQD2 of 90 - 95 Gy while respecting organ-at-risk dose constraints.

Retrospective planning for both source models was performed within the same treatment planning system (BrachyCare) to ensure consistency of target and organ-at-risk volumes and to eliminate potential inter-system variability. The Ir-192 source model was imported and commissioned in the same TPS as the eBx source model prior to retrospective planning. TG-43 dose-calculation parameters, including air-kerma strength, dose-rate constant, geometry function, radial dose function, and anisotropy function, were verified against published consensus data from the High Energy Brachytherapy Source Dosimetry (HEBD) Working Group.

Point dose-rate calculations at multiple radial distances and polar angles demonstrated agreement within ±1%, confirming correct implementation of the TG-43 formalism.

For each patient, the Ir-192 plans were optimised to match the PTV D90 of the corresponding eBx plans as closely as possible. Following target dose matching, organ-at-risk dose metrics were extracted and compared between the two source models.

2.4.2. Measurement

The measurement datasets were extracted directly from the TPS itself. After patients' plans were generated, the analyses of the Dose Volume Histogram (DVH) were done to obtain the maximum doses to 2 cc of the OARs (rectum D2cc and bladder D2cc). Thus, for each patient there were two data points, namely the bladder and rectum doses.

2.5. Data Analysis

After the data was collected, the percentage difference was calculated between the Ir-192 and Xoft source model D2cc's for the OARs. The percentage difference was used since the prescription dose or D90 of the PTV varied greatly between the ten patients.

After this, a Shapiro-Wilk test was done to confirm the normality of the data. The data was found to be normal, and a paired t-test (with $a = 0.05$) was done to test the hypotheses.

3. Results

As a preliminary step, a visual inspection of the dose distributions of eBx and Ir-192 was done and can be seen in Figures 1-6. These views are a good representation of the overall dose distribution in the patient, and illustrate the axial, coronal and sagittal views of both source models around the treatment location. Figure 1, Figure 3, and Figure 5 represent the initial eBx plans, whereas Figure 2, Figure 4, and Figure 6 represent the re-planned Ir-192 plans.

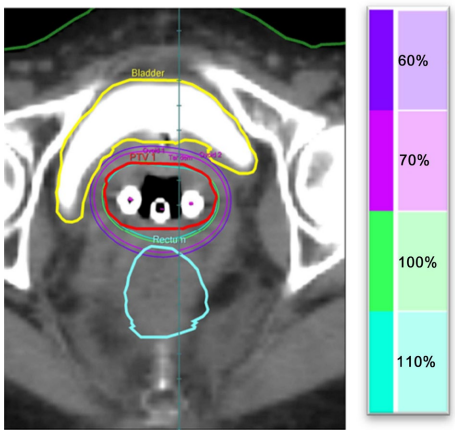

Figure 1. Axial view of the eBx dose distribution.

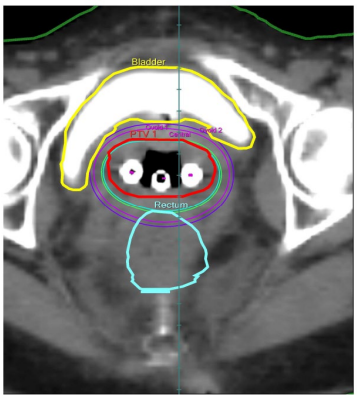

Figure 2. Axial view of the Ir-192 dose distribution.

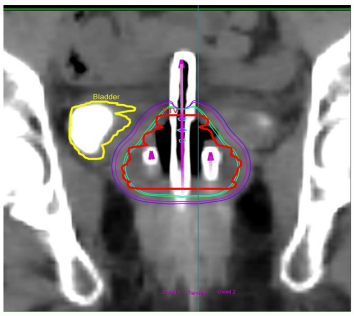

Figure 3. Coronal view of the eBx dose distribution.

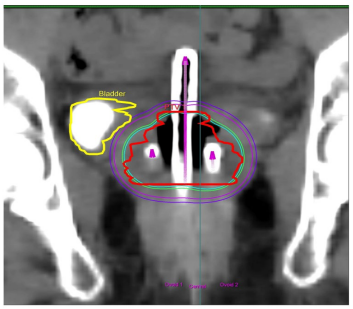

Figure 4. Coronal view of the Ir-192 dose distribution.

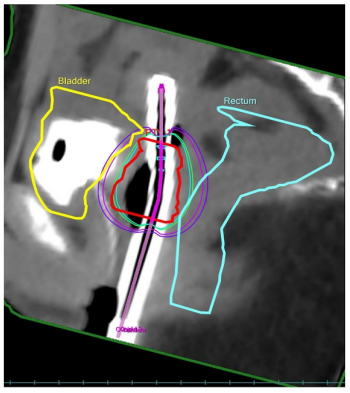

Figure 5. Sagittal view of the eBx dose distribution.

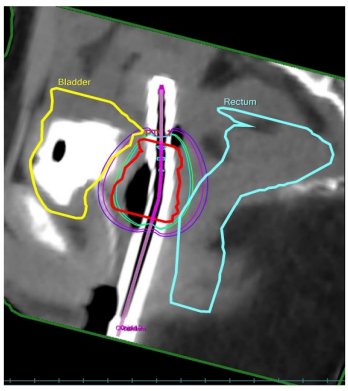

Figure 6. Sagittal view of the Ir-192 dose distribution.

To quantify the dose falloff difference between the two models, the distance between the source and the 10% - 100% isodose lines was determined for Ir-192 and eBx. The dose was normalised at 2 cm and the distances from the source axis to each isodose line were plotted in Figure 7.

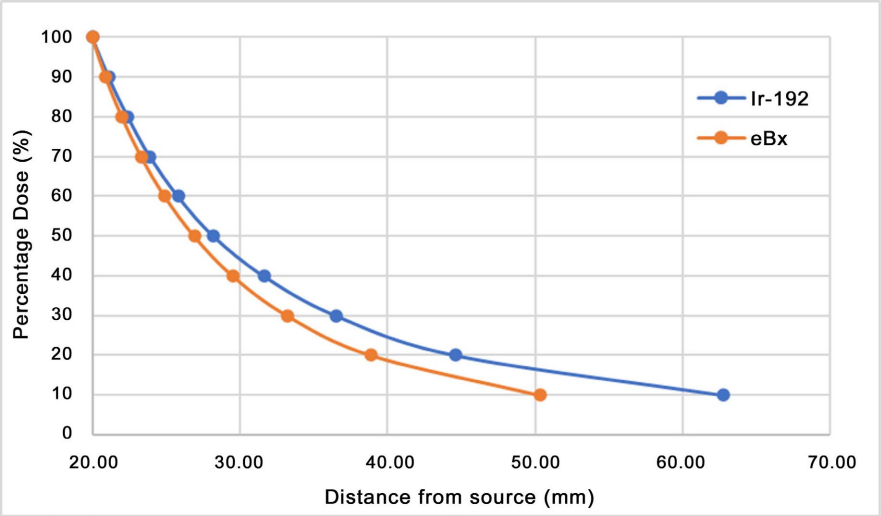

Figure 7. Percentage dose as a function of distance from the source for eBx and Ir-192.

One of the patients' Dose Volume Histogram (DVH) for both eBx and Ir-192 plans was combined and can be seen in Figure 8.

The DVH statistics (OAR D2cc) of all the patients were collected for both source models and these planned OARs doses for both eBx and Ir-192 are shown in Figure 9.

4. Discussion

Overall, in Figures 1-6, the eBx dose distributions were found to be more conformal than the Ir-192 dose distributions when the 110%, 100%, 70%, and 60% isodose lines were considered. It was also confirmed by Morbid *et al.* (2015), Lazares-Cordero *et al.* (2019) and Dickler *et al.* (2008) in their reports, when comparing

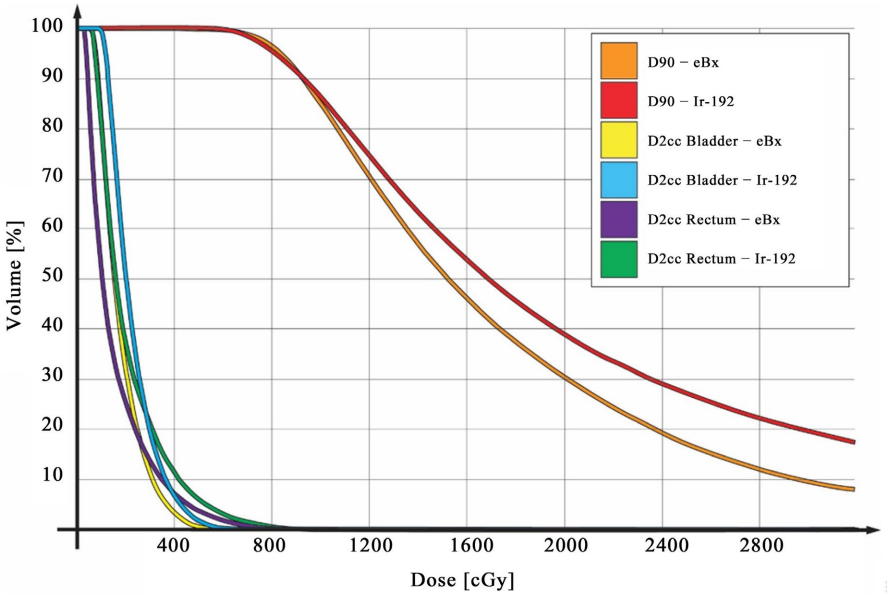

Figure 8. Combined DVH for eBx and Ir-192 source models.

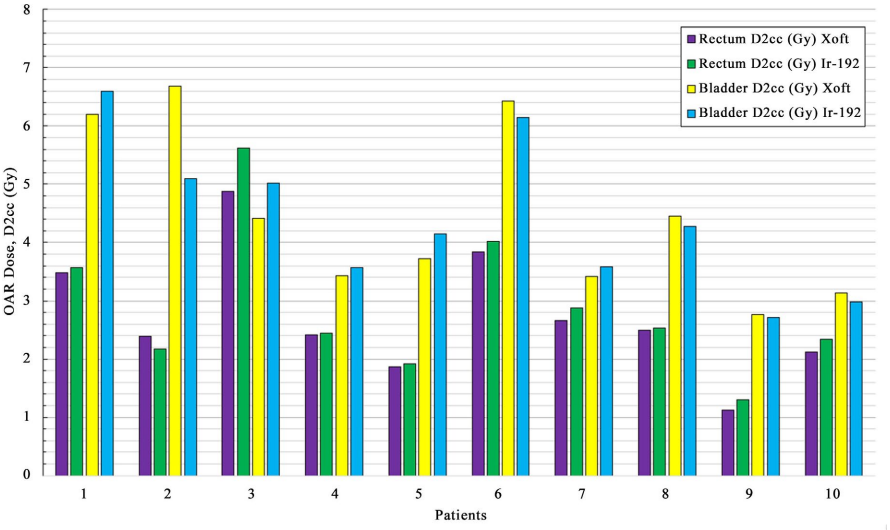

Figure 9. TPS doses for the PTV, the rectum and bladder for both the Ir-192 and Xoft source models.

eBx and Ir-192 dose distributions, that the eBx dose distribution is more conformal than the Ir-192 dose distribution. Together with these experimental results and claims, it can also be physically understood by inspecting the comparison of the radial dose function of the two different source models. Rivard *et al.* (2006) compared the radial dose function for a few source models, and found that the 50 kV eBx source model has a much quicker fall-off than the Ir-192 model. This sharper fall-off can be attributed to the lower energy of 50 kV compared to the higher energy of Ir-192 (ranging from about 136 keV to 1.06 MeV), resulting in more rapid dose attenuation with distance for the eBx source [20].

From **Figure 7**, it can be seen that eBx had a sharper falloff than Ir-192 beyond

the normalisation point. The fact that the eBx dose falloff is sharper due to the radial dose function difference as noted by Rivard *et al.* (2006). It is also noticeable that the difference in distances grows larger at lower isodose levels. This discrepancy can be attributed to the variations in the radial dose function, as previously discussed.

For the patient DVH as illustrated in Figure 8, and most others the eBx dose–volume histograms lie below the corresponding Ir-192 curves for both the bladder and rectum over the majority of the dose range, indicating lower volume exposure at comparable dose levels. Conversely, although the PTV dose coverage was not considered in this report, the eBx DVH demonstrates higher dose levels for the PTV compared to Ir-192, with differences of up to approximately 9 Gy. Figure 8 can also be explained in the work done by Rivard *et al.* (2006) on the radial dose functions of the different sources.

For the rectum, the mean D2cc was **2.52 ± 1.05 Gy** for eBx and **2.78 ± 1.16 Gy** for Ir-192. For the bladder, the mean D2cc was **4.27 ± 1.46 Gy** for eBx and **4.36 ± 1.24 Gy** for Ir-192. The average OAR dose percentage differences in Figure 9 for eBx and Ir-192 were found to be 5.31% ($p \leq 0.05$) and 0.11% ($p > 0.05$) for the rectum and bladder respectively. A statistical analysis (paired t-test with 95% confidence) showed that the calculated average percentage difference between the planned doses (D2cc) for the rectum was statistically significant (5.31%), whereas bladder average percentage difference results were insignificant (0.11%). It is important to note that the Ir-192 source model delivered the higher doses in both cases, but it can be deduced that the eBx bladder D2cc would be the same as the Ir-192 bladder D2cc in the population. This means that the Xoft Axxent 50 kV electronic brachytherapy system delivered less dose to the rectum and equal dose to the bladder when compared to an Ir-192 system.

The results indicate that the eBx system does not deliver higher doses to Organs At Risk (OARs), namely the bladder and rectum, compared with the Ir-192 source model, and is therefore not inferior to Ir-192 when considering OAR D2cc metrics alone. Lozares-Cordero *et al.* (2019) similarly reported a statistically significant reduction in rectum D2cc for eBx (approximately 19%), while no significant difference was observed for the bladder. The difference in reported percentage reductions may be attributed, in part, to differences in organ delineation practices. In the study by Lozares-Cordero *et al.*, the sigmoid colon was contoured and included in the analysis, whereas at SBAH the sigmoid colon is not routinely contoured for brachytherapy planning. Given the steep dose gradients associated with intracavitary brachytherapy, inclusion of additional cranial bowel volumes, such as the sigmoid colon, increases the likelihood that the highest-dose 2 cc originates from tissue located closer to the source. Exclusion of the sigmoid therefore restricts the D2cc evaluation to the inferior rectal volume, which may systematically reduce the measured rectum D2cc and contribute to inter-study differences. The findings of this study confirmed the literature regarding the use of electronic brachytherapy compared to traditionally used radioactive sources. The results showed

that electronic brachytherapy can be used safely with confidence that the OARs are not getting more dose than with Ir-192 models. The significance of these results is that this treatment technique (eBx) can be recommended to other facilities, especially those that want to instate brachytherapy treatments without necessarily having the budget/funding for traditional remote-afterloaders and their required bunkers.

Due to the facts that there is no radiation leakage when the system is off, no radioactive waste, no source issues with source transportation, relatively stable output throughout the life of the x-ray tube and reduced exposure to staff, eBx proves not only as a viable brachytherapy method, but also as advantageous in some instances [11]. Electronic X-ray sources with low kilovoltage require significantly less shielding compared to Cobalt-60, Caesium-137 and Iridium-192 sources, which demand heavily reinforced, bunker-style shielding. This makes eBx system much more viable option for facilities in lower-income regions.

5. Conclusions

To test whether or not electronic brachytherapy is inferior to HDR Ir-192 brachytherapy in terms of doses to the Organs At Risk (OARs), ten cervical cancer patients who were treated with the Xoft Axxent electronic brachytherapy system at SBAH were re-planned retrospectively with an Ir-192 source model using the same planning target volumes and OAR volumes. The results, together with statistical analysis of the results, showed that there was no statistically significant difference between the maximum doses to 2 cm^3 (D2cc) of the bladder when comparing the two source models (eBx vs. Ir-192). The rectum doses, however, present a statistically significant difference. The rectum D2cc was on average 5.31% higher for the Ir-192 plans. This means that the electronic brachytherapy system delivers equal doses to the bladder and lower doses to the rectum compared to an Ir-192 system. This in turn means that the eBx system is non-inferior to the previously used Ir-192 system.

These findings highlighted that electronic brachytherapy could serve as a viable option to Ir-192 brachytherapy for treating gynaecological cancers. It has the potential to offer access to brachytherapy in regions where conventional HDR BT is not available, due to lack of budget/funding. Although the eligibility and safety of this approach have been established in these findings, more prospective research is needed to define the tumour coverage and long-term toxicity.

Ethical Considerations

The study was conducted following approval from the University of Pretoria's Faculty of Health Sciences Research Ethics Committee (Ethics Reference No.: 141/2023).

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Conflicts of Interest

The authors declare no conflicts of interest.

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