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Image-guided radiation therapy (IGRT) in prostate cancer in México, survey of SOMERA (Sociedad Mexicana de Radioterapeutas/Mexican Society of Radiation Oncologists) with recommendations on its implementation and process

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ABSTRACT

Background: Prostate cancer is one of the main tumors worldwide, its treatment is multidisciplinary, includes radiotherapy in all stages: curative, radical, adjuvant, salvage and palliative. Technological advances in planning systems, image acquisition and treatment equipment have allowed the delivery of higher doses limiting toxicity in healthy tissues, distributing radiation optimally and ensuring reproducibility of conditions. Image-guided radiotherapy (IGRT) is not standard in guidelines, only recommended with heterogeneity in its own process.

Materials and methods: A survey was conducted to members of the Mexican Society of Radiation Oncologists (SOMERA), to know the current status and make recommendations about its implementation and use, taking into account existing resources.

Results: Responses of 541 patients were evaluated, 85% belonged to the intermediate-high risk group, 65% received adjuvant or salvage radiotherapy (RT), 80% received intensity-modulated radiation therapy (IMRT) using doses up to 80 Gy/2 Gy. Cone beam computed tomography (CBCT) was performed on 506 (93.5%), (100% IMRT) and 90% at a periodicity of 3–5/week. 3D treatment with 42% portal images 1/week. Online correction strategies (36% changes before treatment), following a diet and bladder and rectal control. Evidence and recommendations are reviewed.

Conclusions: IGRT should be performed in patients with prostate cancer. In Mexico, despite limitations in the distribution of human and technological resources, it is routinely applied. More information is still needed on clinical evidence of its benefits and the process should be implemented according to infrastructure, following institutional guidelines, recommending to report the initial experience that helps to standardize national conduct.

Key words: IGRT; prostate cancer radiotherapy; Mexico

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Introduction

Prostate cancer ranks fourth in frequency worldwide (with more than 4 million cases), after breast, lung and colorectal cancer, and is the second most frequent cancer in men. With an incidence of 28.9 cases/100,000 population, by 2020 there will be an estimated 1,414,259 new cases (7.3% of all can-

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cer patients). 1/7 men in the United States and 1/25 worldwide will have prostate cancer during their lifetime. It ranks 8th in mortality with 375,304 estimated deaths (3.8% of all patients in 2020). The regions with the most cases are Northern and Western Europe, Caribbean, Australia/New Zealand, North America and Southern Africa. The lowest number of cases is found in Asia and North Africa. The incidence in developed countries is 37.5 and in underdeveloped countries 11.3/100,000 population (3:1 ratio). The highest mortality is found in sub-Saharan Africa and the Caribbean. In Mexico, according to the World Health Organization in 2020, it was the most diagnosed cancer, with 261,244 cases, equivalent to 14.5% of new cases (56.6 per 100,000 population). In addition, the reported 5-year prevalence was 799,789 (18.3% of all cancer cases), second only to breast cancer (809,327 cases, 18.5%). It has been reported that 96.8% occurs in people over 50 years of age, occupying the first place in those over 70 years of age. In relation to mortality, it occupies fourth place, with 64,872 deaths (8.1% of the total), after lung, colorectal and breast cancer. Regarding its mortality, it has occupied the first places in the country, for example in 2020, according to INEGI, prostate cancer ranked first in cancer mortality in people ≥ 60 years old, with a death rate of 10.89 /10,000 population.

Its treatment depends on patient factors such as age, comorbidities (as a whole life expectancy) and patient's wishes, as well as on tumor characteristics such as clinical stage, Gleason score and prostate-specific antigen value. Currently, most cases are diagnosed in early stages, where several therapeutic options are available, side effects influence the therapeutic decision. In general, in early stages of low risk, patients can be monitored, operated or receive medical treatment based on hormone therapy or radiotherapy, depending on their life expectancy; in intermediate and high risk stages, radiotherapy is part of the standard management, either as radical treatment, alone or in conjunction with hormone therapy, or as adjuvant or salvage treatment after surgery.

In the case of radiotherapy treatment, technological advances have made it possible to have highly sophisticated image acquisition and treatment equipment, as well as planning systems that allow dose escalation using highly conformal techniques; however, increasing the dose also increases the risk of toxicity in healthy peripheral tissues as well as the probability of geometric uncertainties leading to underdosing in the target volume.

Therefore, a series of factors must be considered to optimize the precision of treatment administration, in order to distribute the dose in therapeutic volumes and limit it in organs at risk (OAR), such as the rectum and bladder.

Image-guided radiation therapy (IGRT) can be defined as the use of image acquisition to increase precision and accuracy throughout radiation therapy treatment, resulting in modification of positioning or anatomical parameters to reduce geometric uncertainty, improve therapeutic goals and/or decrease the risk of associated morbidity, Therefore, the Mexican Society of Radiation Oncologists (SOMERA) board during 2020–2022 decided to evaluate the current situation regarding the IGRT use in one of the most prevalent cancers in our country, considering that prostate cancer benefits from both dose escalation and limiting this high dose to the surrounding tissues such as the rectum and bladder, and the improvement in the quoted therapeutic index is facilitated by IGRT. It is of paramount importance to find out first if is performed across the country and under which circumstances and, then, how it is made and what actions are taken with the data obtained. Finally based on that information, SOMERA will suggest recommendations about its implementation and optimal use.

The IGRT process is much more complex than acquiring images prior to radiation administration to ensure localization, as it includes the delineation of therapeutic volumes [gross tumor volume (GTV), clinical target volume (CTV), internal target volume (ITV), planning target volume (PTV)], organ at risk (OAR), use of 4D imaging, a planning system, as well as the adaptation of the treatment to anatomical-biological and positional changes that occur in each patient throughout each session.

The clinical objectives when employing IGRT are: reducing the treatment margin, increasing the dose per fraction, increasing the total dose (dose escalation) and monitoring anatomical changes in order to perform adaptive radiotherapy.

The components that any IGRT system should contain are: image acquisition system, set of reference images for comparison, software for image incorporation and protocol correction method [12].

A systematic error is one that will have an effect throughout the entire treatment, for example, during the simulation, delineation, planning or positioning process, and may affect the treatment outcome if not corrected. A random error occurs in the execution of the treatment and varies with each fraction, it may occur peripheral to the dose distribution of the planned volume.

There are several algorithms for the establishment of IGRT. The correction methods are: on-line where image information is analyzed immediately after acquisition with correction before each treatment, resolving systematic and random errors. Offline, where the image information is stored, analyzed and corrected afterwards, resolving systematic but not random errors, as it is not performed immediately but sequentially every 3–5 fx, which is why it must be performed in at least 10% of the total number of sessions. Both have advantages and disadvantages, while online is preferred in case of PTV close to OAR (non-parallel function), dose escalation or hypofractionated scheme applied in radical, adjuvant or salvage prostate cancer scenario and for IMRT or stereotactic body radiation therapy (SBRT) techniques; the disadvantage is the increase in workload, RT time and radiation dose. In the case of off-line, its advantage is that the correction is performed if the error exceeds the tolerance margin selected by correcting the average error in N fractions, besides being more cost effective due to the lower use of images. Both systems are effective and the radiation oncologist must choose the one that best applies to his or her patients and institution, since each treatment is individualized and so is also its IGRT method.

There is heterogeneity in the distribution of linear accelerators in the country, with most of them concentrated in Mexico City, followed by large cities such as Guadalajara and Monterrey, also pointing out the socioeconomic differences. There is no clinical regulation regarding the type and frequency of IGRT by tumor type, following institutional protocols according to hospital. However with information from private and public centers, we have the necessary data to know the current status of IGRT in Mexico.

Materials and methods

We sent a survey to active (272) members of the SOMERA to learn about IGRT measures implemented and performed on prostate cancer patients treated during the last year period (2021) in the country. In addition, we performed a literature review in order to make recommendations regarding its use, mainly based on the obtained results.

Results

Information was obtained from 541 patients. The Table 1 describes data on the risk group, treatment objective, type of radiotherapy used, average dose according to type of radiotherapy, inclusion or not of pelvic lymph node regions, use of diet, control of OAR (organs at risk of toxicity) filling, use of IGRT strategy, type of IGRT, frequency, correction measure and percentage of treatment adjustment.

Figures 1–4 show the results according to risk groups, treatment objectives, radiation types as well as IGRT types.

Figures 5–10 Show PTV and OAR volumes and how the change in rectum volume could affect

Table 1. Results, characteristics of the 541 evaluated patients

Variable	Number of cases (percentage)
Low risk	78 (15%)
Intermediate risk	194 (37%)
High risk	248(48%)
Radical Rt	190 (35%)
Adjuvant Rt	151 (28%)
Rt salvage	200 (37%)
Conformed Tx	84 (19%)
IMRT	433 (80%)
SBRT	7 (1%)
Maximum dose 3D /fraction	76 Gy/ 2 Gy
Maximum IMRT dose/fraction	80 Gy/ 2 Gy
Maximum SBRT dose /fraction	36 Gy/7Gy
Use of diet	541 (100%)
Empty rectum	447 (83%)
Full bladder	541 (100%)
IGRT	541 (100%)
CBCT	506 (93.5%)
Daily CBCT	442 (82%)
CBCT 3/week	44 (8%)
CBCT 1/week	55 (10%)
Portal verification	35 (6%)
Portal image frequency 1/week	35 (6%)
Cases requiring correction	193 (36%)

RT — radiotherapy, Tx — treatment, IMRT — intensity-modulated radiation therapy; SBRT — stereotactic body radiation therapy; 3D — conformal, IGRT — image-guided radiation therapy; CBCT — cone beam tomography

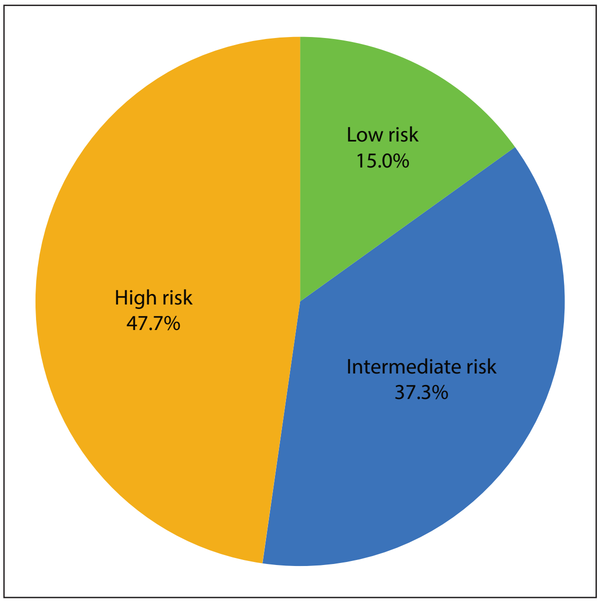

Figure 1. Distribution by risk group

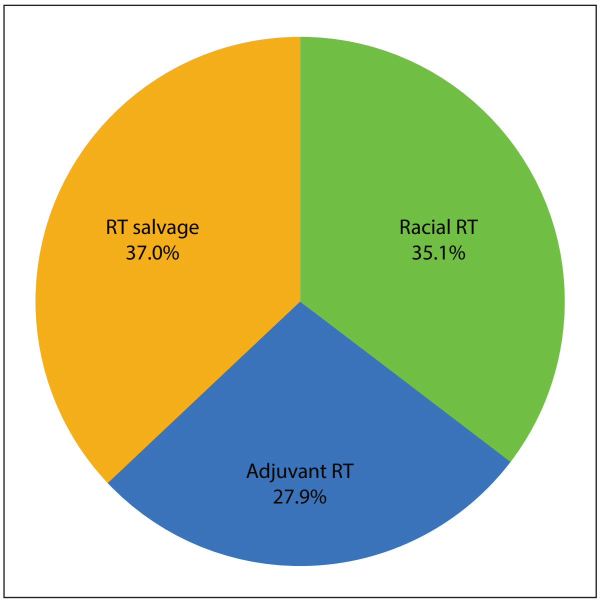

Figure 2. Distribution by treatment objective. RT — radiotherapy

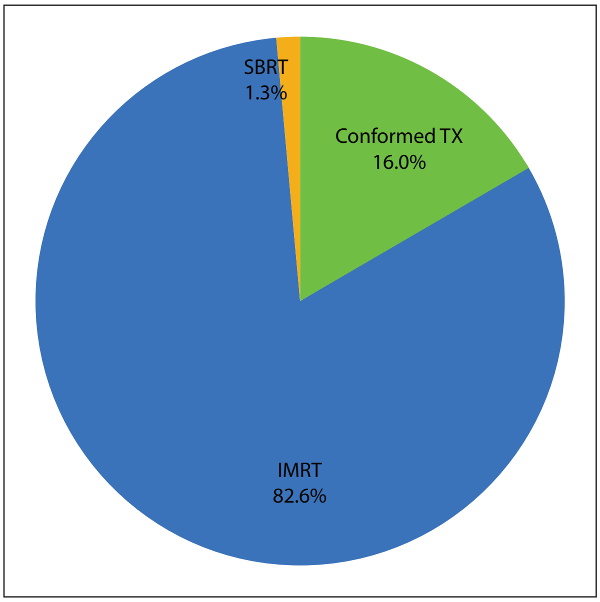

Figure 3. Distribution by radiation's type. SBRT — stereotactic body radiation therapy; IMRT — intensity-modulated radiation therapy; **TX —**

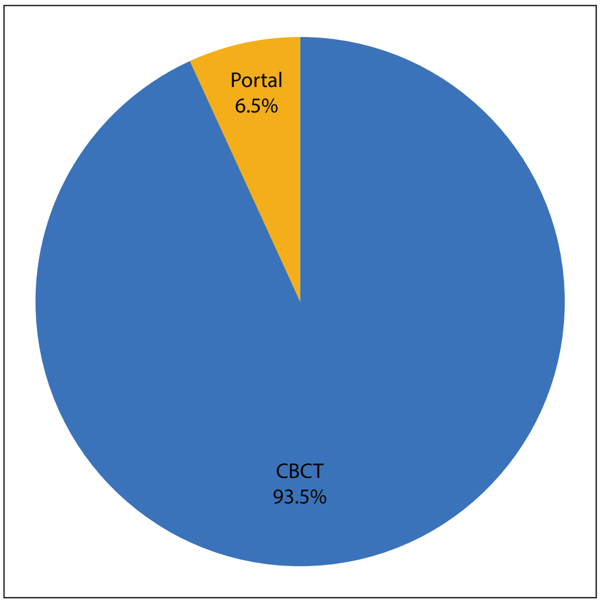

Figure 4. Distribution by image-guided radiation therapy (IGRT) type. CBCT — cone beam computed tomography

dose distribution in axial and sagittal views, also how changes in bladder fullness could change bowel volumes without affecting pelvic nodes volumes.

The results in terms of type of prostate cancer cases, show a reflection of the daily casuistry, with a large number of cases belonging to intermediate and high risk categories sent for adjuvant or salvage radiotherapy, while an interesting finding is that the vast majority were treated with intensity modulated radiotherapy, reaching dose escalation of up to total doses of 80 Gy in fractions of 2 Gy.

Regarding IGRT measures, all of them are online strategies. For 90% of IMRT cases a frequency of 3–5 times per week is found while for conformal treatments in 42% portal imaging was performed at least 1 time per week. Corrections prior to treatment administration were performed in 36% of cases, 83% of patients were instructed in some type of diet with

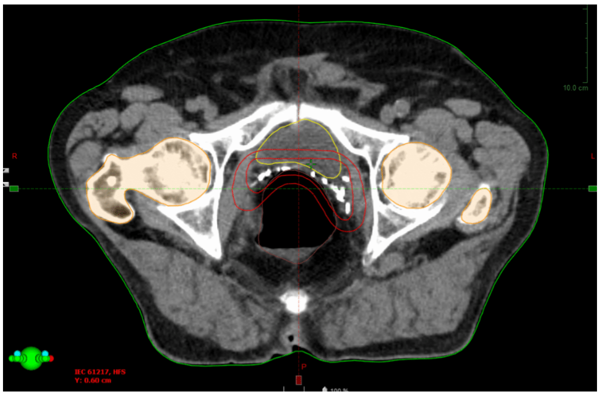

Figure 5. Axial slice showing planning target volumes (PTVs), and organs at risk (OARs) (bladder, rectum) with a distended rectum

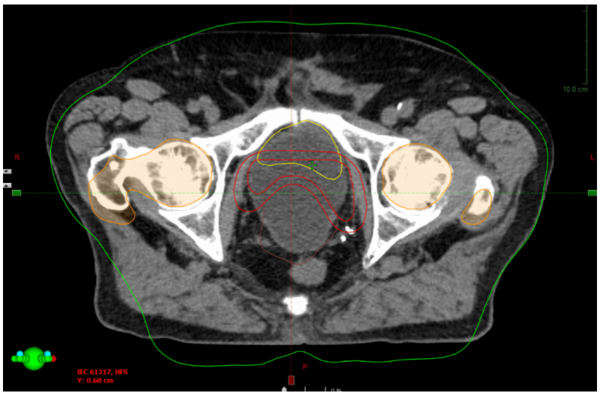

Figure 6. Axial slice showing planning target volumes (PTVs), and organs at risk (OARs) (bladder, rectum) with an empty rectum, notice how the PTV is displaced and now includes part of the filled bladder

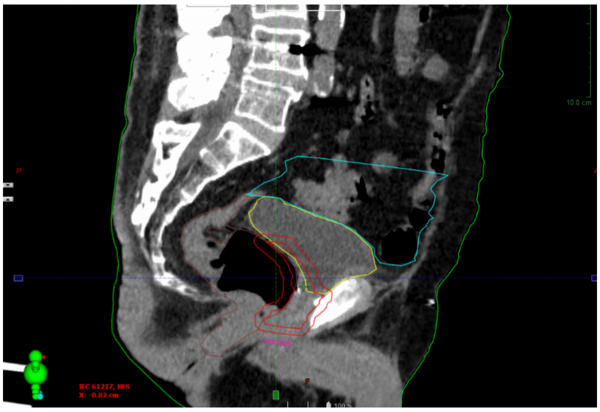

Figure 7. Sagittal slice showing showing planning target volumes (PTVs), and organs at risk (OARs) (bladder, rectum) with a distended rectum

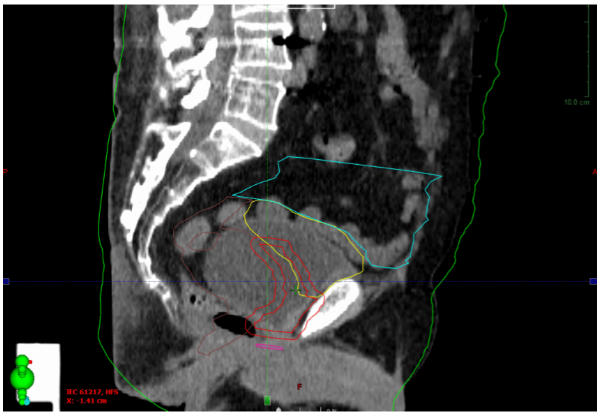

Figure 8. Sagittal slice showing planning target volumes (PTVs), and organs at risk (OARs) (bladder, rectum) now with an empty rectum

rectal emptying, while 100% were instructed regarding bladder filling.

As previously described, all prostate cancer patients are evaluated with some type of IGRT although the details of correction in different axes (by type of displacement) were not obtained. However, it is worth highlighting the effort of the multidisciplinary team (nurse, radiotherapist, medical physicist and radiation oncologist) to control patient variables (diet, bladder filling control, rectal emptying), as well as the performance of CBCT prior to intensity-modulated radiotherapy, with immediate correction of volume adjustment and/or displacements.

Discussion

IGRT is not something new, with the first records of it coming from 1969. It was then performed through the acquisition of megavoltage images, which only allowed considering bone structures.

Improvements in planning systems and radiotherapy equipment have resulted in more conformal dose distributions and sharper dose gradients, so it is necessary to ensure reproducibility not only of bony structures but also of internal anatomy, ideally in all techniques, but indispensably as conformality increases: 3D, intensity modulated radiotherapy (IMRT), stereotactic body radiotherapy (SBRT) and protons. Thanks to kilo-voltage imaging systems, such as CBCT, we have been able to compare soft structures simultaneously.

With these modalities there is a risk of geographic loss 10, including errors in PTV delineation, poor image quality [tomographic, magnetic resonance imaging (MRI) or positron emission tomography

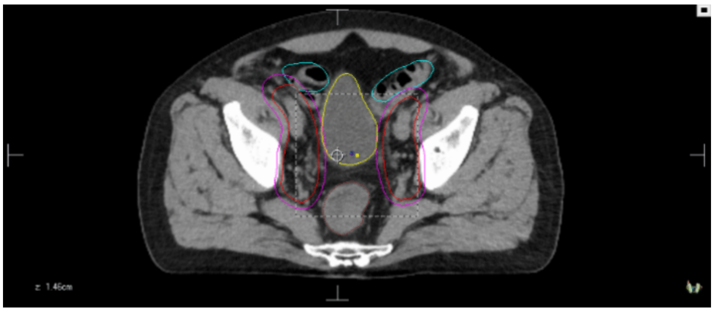

Figure 9. Axial slice showing planning target volumes (PTVs) (pelvic lymph nodes), and organs at risk (OARs) (bladder, rectum, bowel) with an controlled filled of both bladder and rectum

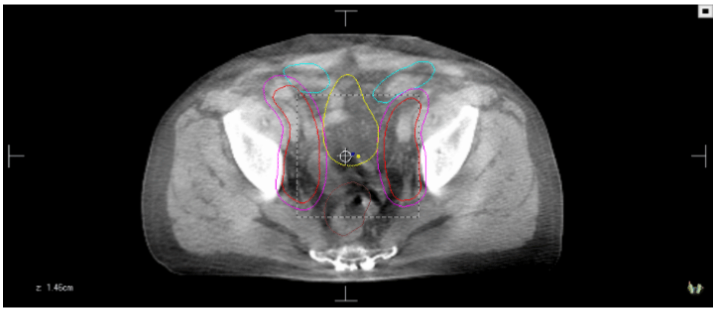

Figure 10. Axial slice showing planning target volumes (PTVs) (pelvic lymph nodes), and organs at risk (OARs) (bladder, rectum, bowel) now with an empty bladder, notice how the small bowel is within the bladder volume, although the pelvic lymph node area still with no changes respect the planning volume in a cone beam computed tomography (CBCT) image

(PET)], inter- and intra-observer variability, volume definition, errors in image incorporation. Errors in patient positioning: There are variations according to immobilization method, e.g. mattress *vs*. skin tags only, pelvis *vs*. pelvis and legs fixation, abdominal compression techniques, prone position increases risk, as well as body mass index, respiration, etc. There are also changes in the PTV position: due to prostate deformity during the course of treatment, which is influenced by the use of hormonal treatment and previous transurethral resection, mobility due to differences in filling or distension of the rectum and bladder. Changes in volume of the rectum are more important than those in the bladder, with greater changes in the anterior-posterior direction than in the cranio-caudal and right to left, and with a greater variation at the base of the prostate than in the apex. It is considered that diet does not have a greater impact nor do rectal spacers, however, the endorectal balloon can improve reproducibility, mainly in prolonged sessions; with respect to the bladder. It is believed that filling control protocols are not necessary to improve prostate stability, however, there is a dosimetric advantage since it displaces the intestine from the high dose area. Another aspect is therapeutic volumes that include lymph node regions and seminal vesicles, which have their own challenges as they have independent motion and may be fixed initially as they are invaded by tumor and change during the course of treatment. These variations can be interfraction, from one session to another, or intrafraction, movement during radiation. Depending on the modality used, one error may have greater clinical repercussions than another, for example, in the case of conventional radiotherapy where about 38 fractions are used in intermediate or high risk patients, interfraction variations can be corrected in consecutive sessions, while the higher doses used in SBRT combined with longer times and fewer sessions have both impacts of interfraction and intrafraction changes. In addition, there is the added complexity of adding volumes such as the seminal vesicles and lymph nodes in patients who will receive hypofractionated schedules.

Adaptive radiotherapy is achieved by verifying location and changes in therapeutic volumes (VT) and OAR, real-time monitoring of the tumor and taking measures according to its findings.

Methods of surrogate fitting are: use of fiducials, external markers, visualization of anatomical variables by imaging (fluoroscopy, CT with Kv or MV, MRI, US, X-ray, electromagnetic localization and optical surface imaging).

Extra radiation doses due to IGRT should be taken into account, American College of Radiology (ACR) American Society for Radiation Oncology (ASTRO) report in 2020 stated that Planar Imaging (kV) delivers doses of 0.1 to 0.6 mGy, Planar Imaging (MV) — 1 to 3 cGy, 3D X-Ray — 10–50 mGy, while for 4-D Imaging or tracking with radiation systems the cumulative dose should be reviewed, Fluoroscopy reaches up to 1000 mGy/h, more frequent and advanced Imaging Vg. CBCT, fluoroscopic cine imaging with MV, increases the detrimental dose to the patient, so it has been pointed out by ACR-American Association of Physicists in Medicine (AAPM) that "The frequency of IGRT should be carefully balanced between tumor/technique needs, imaging dose and resource requirements".

This is why complexity can be considered a risk, as the belief that the more IGRT systems are implemented in the clinic the better for clinical evolution is true in theory, however, difficult to materialize in practice. If hospitals do not have sufficient machine-time and human resources to handle the added complexity, or implement more complex IGRT procedures without sufficient resources, it can potentially lead to more errors and, eventually, degrade the quality of the RT program.

A survey of ASTRO members, with 601 evaluable responses, showed an increase in the use of IGRT despite the lack of evidence to improve evolution or reduce toxicity. In 2009 it was used in 93.5% of cases, and although it prevails, in practice there is no consensus on the ideal sequence and implementation, recognizing wide variations between institutions. They found within their results that IGRT is performed in most sites: the brain, C&C, lung, esophagus, pelvis and prostate, the most used modality was CBCT, and Ca portal imaging only in breast. In terms of frequency, the tumors in the brain or breast were imaged weekly, the rest were imaged daily. There were no differences in margins by subsite, nor by type or frequency of IGRT. Observing a high prevalence of daily CBCT (as expected). They found a wide variability in type of IGRT by specific tumor site, in frequency and verification methodology, with no significant difference in frequency of IGRT or CBCT and margin selection and with poor resident involvement. The authors conclude that the findings describe practices in the US, identifying great heterogeneity in modality, frequency, verification method and PTV expansion. They emphasize that guidelines, consensus, evidence-based approaches, better selection of PTV margins, greater resident involvement are required. Standardized, accessible, safe, timely and cost-effective IGRT procedures must be ensured.

Another very relevant aspect is the cost of IGRT, as reported in a study of 208 patients recruited in 7 French centers. A total of 6,865 fractions were analyzed individually, reporting that more annual time is required in equipment, more immobilization expenses, depreciation and price of equipment, RO payment, technician time, maintenance and QA, payment of physical, and annual physical time for maintenance and QA, RO time and cost of RO time. The average reported total duration of treatment + CBCT was 21.0 min, for electronic portal imaging with fiducial markers (EPI-FM) it was 18.3 min. Increasing the frequency from weekly to daily increased the mean duration by 7.3 min (+53%) for CBCT and by 1.7 min (+10%) for EPI-FM ($p \leq 0.01$) and the mean daily *vs*. weekly additional cost per patient was EUR 679 and EUR 187 for CBCT and EPI-FM, respectively ($p < 0.0001$).

Regarding geographical distribution of countries using IGRT, in United States 95% of RO use and 92% of the teams have IGRT, while according a report of 2014, in Europe only an average of 49% of teams have IGRT: England 35%, Switzerland 20%, Sweden 70%, Spain 19%, France 53% and Holland 95%. In 2009, 75% of academic centers and 50% of private ones used volumetric imaging.

There is no single system that can be applied to all clinical scenarios, as one device is versatile to treat multiple sub-sites, but different sites require different radiation modalities, therefore, different levels of accuracy. In 2D or 3D RT, the portal image (MV) is sufficient for localization as the level of placement accuracy is in cm, but in the case of PTV close to critical structures, daily kV or CBCT reduces uncertainty in mm magnitude. In SBRT or SRS, real-time tracking is considered ideal for monitoring intra-fraction motion.

IGRT is a complex part of the radiation therapy process, as technicians, physicists and ROs spend more time imaging, identifying targets and correcting patient position. The longer the IGRT and analysis time, the more the patient's position may change from the first image acquired, which may require repeating the imaging, prolonging the machine time and staff time involved. These multilevel imaging studies need to be paid for by insurance companies or absorbed by hospitals. The staff present at IGRT must be fully competent in the chosen technology. In addition to additional personnel, more financial resources are required for training or education. However, in theory, better and modern equipment with IGRT allows for more complex treatments, such as SBRT and SRS. Lack of training is the enemy, not complexity. In terms of bunker space, the equipment already has integrated systems and uses wall, floor and ceiling attachments that take up little space, and before acquiring equipment, the IGRT systems needed should be considered based on the needs of the service. Successful implementation in large academic or private centers does not necessarily represent the reality of a country, since there may be institutional centers where most patients are treated and there may be limited personnel, funding and resources for training even the most basic IGRT systems.

Speaking specifically of IGRT in prostate cancer, there is an article where 7 studies were included and the results show that IGRT, independent of the technique used, is not associated with more toxicity and has the potential to reduce associated symptoms. Its use in prostate cancer results in better dosimetry, facilitates diagnosis and management of exceptional deviations including immediate changes and errors, weight loss, limb deformity, systematic changes in internal organs and changes due to respiratory movements, however the use of IGRT in prostate cancer results in higher cost.

Another aspect is the legal one. The patient should be informed that IGRT may involve acquiring images more frequently, with potential higher radiation exposure, depending on the modality used and should be included in informed consent, the patient should know that the RO will seek to use the lowest radiation dose to obtain good image quality.

We acknowledge to all the SOMERA associates who participate in the survey that we have no conflicts of interest or funding sources

Conclusions

With the data obtained from this SOMERA survey, We found out that in Mexico, in spite of the heterogeneity of equipment and its distribution, all patients with prostate cancer who receive radiotherapy undergo some method of IGRT, CBCT with online correction and modifications at the time of treatment being the most commonly used. It is also customary to monitor rectal emptying and bladder filling, as well as diet, although the latter are measures that have not been shown to improve reproducibility. Globally, IGRT has been shown to improve clinical evolution and limit toxicity.

IGRT in prostate cancer is crucial in terms of increasing accuracy in radiation delivery, ensuring reproducibility, optimizing coverage to PTV and limiting high doses to OAR. Each center must develop specific protocols, according to the most frequent pathologies, in the case of prostate according to the incidence of radical treatment, adjuvant or salvage with or without inclusion of seminal vesicles, lymph node areas, based on the technology they have. In order to improve the use of IGRT, which evolves rapidly, training and updating are essential, and also its limitations must be understood, which will ensure improvement in the evolution of patients.

In the era of evidence-based medicine, we should have comparative results between sophisticated IGRT approaches in maximum precision treatments such as SBRT, or hypofractionated *vs.* conventional, so SOMERA recommend reporting national experience in order to improve our clinical practice and homogenize the IGRT patterns across the country.

Conflict of interest

None declared.

Funding

None declared.

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