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Systematic review

Is there a role for endorectal balloons in prostate radiotherapy? A systematic review

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ABSTRACT

Background and purpose: Endorectal balloons (ERBs) are being used in prostate radiotherapy for prostate immobilization and rectal wall (Rwall) sparing. Some of their aspects, however, have been questioned, like patient's tolerance and their value in modern high-precision radiotherapy. This paper gives an overview of published data concerning ERB application in prostate radiotherapy.

Materials and methods: Systematic literature review based on PubMed/MEDLINE database searches.

Results: Overall, ERBs are tolerated well, although patients with pre-existing anorectal disease have an increased risk of developing ERB-related toxicity. Planning studies show reduced Rwall and anal wall (Awall) doses with ERB application. Clinical data, however, are scarce, as only one study shows reduced late rectal damage. There is no consensus about the immobilizing properties of ERBs and it is recommended to use additional set-up and correction protocols, especially because there are potential pitfalls.

Conclusion: ERBs seem well-tolerated and in planning studies reduce anorectal wall doses. This may lead to reduced anorectal toxicity, although clinical studies are warranted to confirm this hypothesis and to further investigate the immobilizing properties of ERBs, preferably in combination with advanced techniques for position verification.

There is a dose–response relationship of prostate cancer in external beam radiotherapy (RT) [1,2]. However, dose-escalation is limited by toxicity of surrounding normal tissues, and improved tumor control might be at the cost of higher toxicity rates [3]. In particular anorectal toxicity has a great impact on patients' quality of life [4].

Three-dimensional conformal radiotherapy (3D-CRT) [5] and intensity-modulated radiotherapy (IMRT) [2] have allowed more conformal dose distributions to the prostate, while selectively sparing surrounding normal tissues. Anorectal toxicity rates in IMRT range from 26% to 73% (acute) and from 5% to 65% (chronic) [6–9].

Despite highly conformal RT, uncertainties due to patient set-up errors and prostate motion [10] require a margin around the clinical target volume (CTV), thus creating the planning target volume (PTV). Minimizing these uncertainties allows smaller margins, thereby reducing the dose to the anorectal complex. However, as 74% of prostate cancer foci are located in the peripheral zone and in the proximity of the rectum [11], care must be taken not to underdose the tumor.

In addition to improved treatment delivery and developments in image-guided RT [12,13], daily inserted endorectal balloons (ERBs) are being used to immobilize the prostate, thereby reducing CTV-to-PTV margins [14–20]. A second reason for ERB application is its Rwall sparing effect by pushing the parts of the rectum away from the high-dose regions [15,19–28].

In this paper, experience with the application of ERBs in prostate 3D-CRT, IMRT, and proton therapy, published in the international literature, is reviewed.

Materials and methods

We performed a systematic literature review based on database searches in PubMed/MEDLINE and included articles up to June 2009. Terms used for the search were 'balloon', 'endorectal balloon', 'rectal balloon', 'rectal catheter' and synonyms combined with one or more of the following: 'prostate', 'prostate cancer', 'radiotherapy', 'radiation', 'IMRT', 'rectal toxicity' and synonyms. Furthermore, these terms were combined with the respective key words for each paragraph. Publications mentioned in the reference list of articles found in the automatic search and considered suitable were manually searched for. Only papers published in English were included.

Results

Types of endorectal balloons

In 1979, for the first time, ERB application in prostate RT was reported [29]. To our knowledge, four different ERBs have been

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described since then, three originating from diagnostic radiology, and one especially developed for RT purposes (Fig. 1).

The first ERB (referred to as ERB1) consists of a 9-cm-long latex balloon fixed on a 33-cm flexible shaft of polyvinylchloride (Medrad, Pittsburgh, PA). It was originally designed as an endorectal coil in magnetic resonance imaging (MRI) and the balloon has a concave shape for optimal conformation to the prostatic-rectal interface. In prostate RT 60, 80, and 100 cc of inflated air have been reported [24,30,31], resulting in balloon diameters of 4.0–4.5 cm. The second ERB (ERB2) is a 5-cm-long silkolatex balloon, fixed on a 30-cm-long two-way rectal tube, made of soft rubber with a silkolatex coating, used for barium enema procedures (Nordmann, Rüsch AG, Kernen, Germany). Balloon diameters with 40 and 60 cc of air are 3.7 and 4.3 cm, respectively [26]. The third balloon (ERB3) consists of a 15-cm-long rigid shaft with a non-latex retention cuff (4.5-cm-long) fixed on it (EZ-EM, Westbury, NY). Air volumes of 60 and 100 cc [22,32] create balloon diameters of 5.5–6.0 cm.

In a direct comparison of these three balloons [24] patients preferred ERB2; inflation of ERB3 was painful in 25%, because of the largest ERB diameter. Technologists preferred the ERB1, as it was easiest to handle and to insert. Insertion of ERB3 was more difficult, because of the rigid, short shaft. Recently, a RT-specific ERB was reported on (ERB4), consisting of a 20-cm-long flexible shaft of polyvinylchloride with a 3-cm-long silicon balloon (QLrad B.V., Dalfsen, The Netherlands) [33]. It is not open-ended and equipped with a stopper and depth markers; inflated with 80 cc of air and its diameter is 6.0 cm.

In addition to different ERB types, both prone [18] and supine [24] treatment positions have been reported.

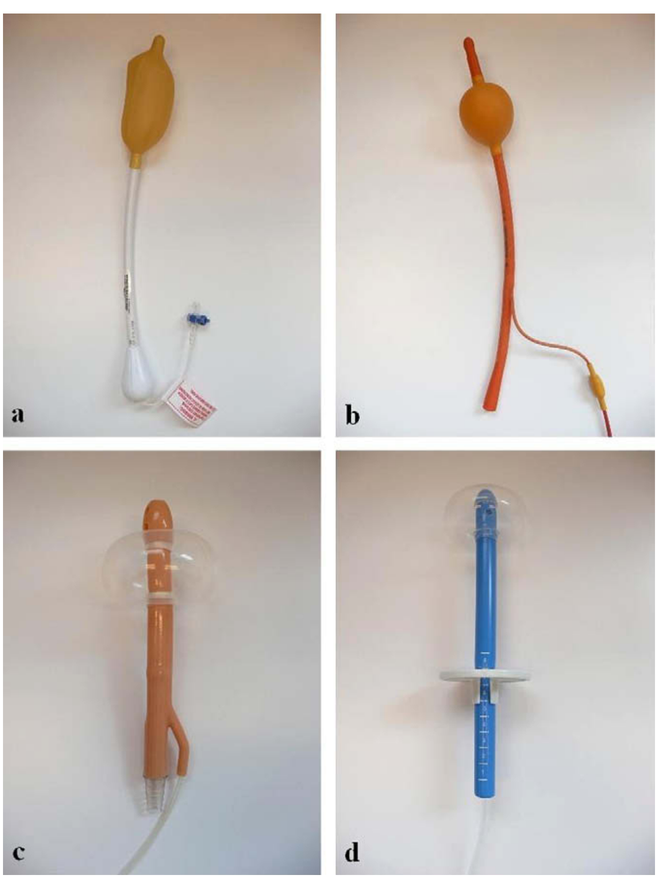

Fig. 1. The endorectal balloons, mentioned in the literature: ERB1 (a), ERB2 (b), ERB3 (c), and ERB4 (d). See text for specifications.

Prostate motion and target localization

The role of ERBs as prostate immobilizers, to reduce interfraction and intrafraction variations in prostate position and thus CTV-to-PTV margins, has been investigated. D'Amico et al. evaluated intrafraction prostate motion by obtaining CT-images at 1-min time intervals, both with and without an air-filled (60 cc) ERB1 in place [14]. They concluded that gland immobilization is possible with ERBs, as the balloon reduced the maximum prostate displacement in any direction from 4 to $\leqslant$1 mm. A reduction in interfraction motion was observed with an air-filled (40 cc) ERB2 in repeated CT-examinations: maximum displacement in the AP direction of >5 mm occurred in 2/10 patients, compared to 8/10 patients without ERB [15]. With a 100 cc air-filled ERB3, only small interfraction displacements were observed. The largest mean (1 SD) displacement was in the SI direction: 0.92 mm (1.78) [17,20]. Additionally, no organ displacement was seen during normal breathing with an ERB inserted. Given this limited prostate motion, smaller CTV-to-PTV margins were advised when using an ERB.

However, not all reports were able to confirm these immobilizing features. No differences in systematic and random prostate deviations were found between patients with and without an 80 cc air-filled ERB1 using fiducial marker-based daily portal imaging [12]. The largest interfraction variation was in the AP direction (4.7 mm, 1 SD), which was attributed to the presence of stool and gas between the ERB and Rwall. In addition, off-line corrections reduced the systematic prostate displacements equally in both groups. Based on these findings, it was concluded that ERB application does not effectively reduce interfraction prostate motion and the use of positioning correction protocols was advocated. A similar recommendation was made for dose-escalation with a 60 cc air-filled ERB2 [34].

Drawing definite conclusions on the immobilizing properties of ERBs is difficult, because of (a) different imaging techniques for positioning verification, (b) differences in imaging frequency, (c) non-uniformity in scoring of variations (e.g. maximum displacements, SDs), (d) variation in patient position, and (e) different ERBs and inflated volumes. Therefore, in accordance with the above-mentioned suggestions, we recommend that, when using ERBs, position verification and correction protocols continue to be used to prevent large day-to-day variations.

As the ERB is situated directly adjacent to the anterior Rwall and can be well visualized by portal imaging [14,15], it can assist in localizing the prostate and thus reduce CTV-to-PTV margins. A posterior field margin of 1 mm behind the anterior ERB surface has been suggested when online portal imaging is used, as the anterior Rwall could be defined with an accuracy of 1–2 mm, which was equal to the maximum AP prostate displacement. [14]. Others confirmed this improved set-up due to ERBs, although they advised more conservative posterior PTV margins: 10 mm in 3D-CRT and 4 mm in IMRT [21,35].

Dosimetric consequences

As numerous reports have described dose-volume and dose-surface relationships of anorectal toxicity [36], several groups have investigated the dosimetric effect of ERBs in an attempt to reduce toxicity.

3D-CRT and IMRT

A 40 cc air-filled ERB2 significantly reduced Rwall doses in 4-field 3D-CRT [15,21], especially high-dose exposure to the posterior Rwall. This phenomenon was attributed to an increased distance between the prostate and the posterior Rwall. However, with seminal vesicles (SVs) included in the target volume, only