

## Introduction

External beam radiotherapy (EBRT) is one of the standard treatments for patients with prostate cancer.

Despite accurate planning and contouring, use of fiducial markers, image guiding and intensity modulated radiotherapy, radiorectitis remains a bothersome and sometimes difficult to treat acute or long-term complication (1-6).

Level one evidence have recently shown that the implantation of a spacer between rectum and prostate reduces the level of radiotoxicity on the anorectal structures and therefore reduces the incidence of radiorectitis (1-3, 5).

However short genitourinary risk and complications such as pain, wound infection, tenesmia, hematuria, LUTS (Lower Urinary Tract Symptoms) are mostly underreported.

We report on the short-term side-effects that appear when implanting a biodegradable balloon as spacer between rectum and prostate.

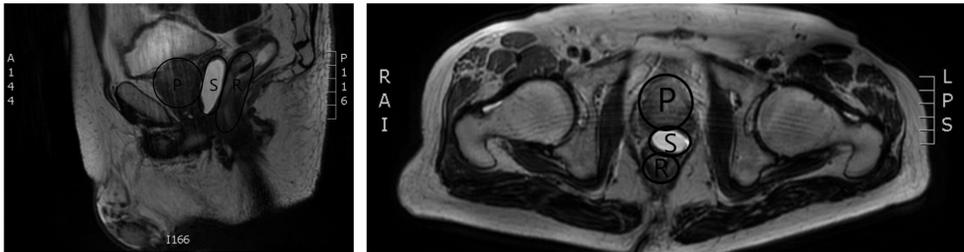


Image 1: MR T2 image of the pelvis with visualization of the Spacer (S) between prostate (P) and rectum (R).

## Methods

Five patients with prostate cancer classified as intermediate or high risk, according to the D'Amico classification, were selected. The inclusion criteria for the implantation of balloon-implants did not differentiate of those for external radiotherapy and the implantation of gold markers. Patients gave informed consent and antibiotic prophylaxis was given.

All patients received gold fiducial markers intra- prostatic in combination with an extra-rectal BioProtect® balloon implant of a biodegradable material. These implants were placed from a perineal approach under general anesthesia. The balloon was inflated with a physiological fluid at the end of the surgery. Transrectal ultrasound was used to guide for a correct positioning between prostate capsule and rectal mucosa. The implantation was timed four weeks ahead of the start of the radiotherapy treatment.

During the first weeks after implantation, the patients were followed closely by the radiotherapist and/or urologist and systematically interrogated about pain symptoms using the VAS (Visual Analogue Scale) score, tenesmia, fever, LUTS (Lower Urinary Tract Symptoms) and hematuria or rectal bleeding.

	Age (years)	PSA (ng/ml)	Gleason- score	TNM- classification
Patient 1	71	7.91	4+3	cT2b NOM0
Patient 2	73	5.74	4+3	cT2a NOM0
Patient 3	77	12.5	4+3	cT2b NOM0
Patient 4	82	14.69	3+3	cT2b NOM0
Patient 5	83	45.4	4+4	cT2c NOM0

Results - Table 1: patient demographic

## Results

For the observation of short-term side-effects, patients were followed during a period of four weeks.

Two patients (patients 2 and 4) experienced a urinary retention in the first 12 hours after the implantation of the implant. This resulted in a one-off transurethral catheterization and an overnight stay in the hospital. The other three patients were discharged in the evening as planned.

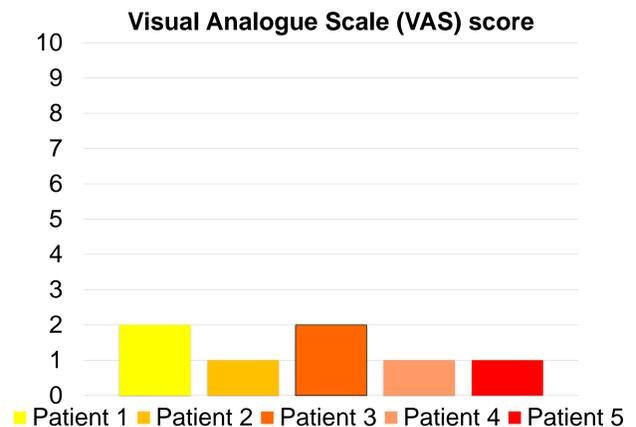
None of the patients had problems of wound healing, infection or elevated temperature in the days post-operatively.

In the following weeks, none of the patients reported any new LUTS. There was no clear change in the urinary frequency, by day or by night. There did not occur a secondary urinary retention or clear dysuria. No hematuria was observed.

Patients did not report changes in stool frequency, constitution or tenesmia. There did not occur an episode of rectal bleeding.

All patients reported a mild discomfort they scaled lower than 3 on the VAS-scale. This discomfort did not affect their lifestyle or quality of life.

Patients could all start with the radiotherapy as planned without any major complications or continued discomforts.



## Conclusions

Implantation of biodegradable balloon spacers in patients who receive primary radiotherapy for prostate cancer is safe.

Among the reported complications were urinary retention post-operatively and mild discomfort (VAS ≤2), but without significant or continued effect on the quality of life.

A prolonged follow up of a large group in combination with further research on this subject is needed to observe the possible long-term side-effects of this technique for the prevention of radiorectitis.

## Bibliography

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