795

Transperineal Approach Insertion of Pro-Space, A Novel Biodegradable Inflatable Balloon System for Prostate Cancer Radiotherapy: Results of 24 Cases from a Prospective Multi-Center Study

*F. Dal Moro[1], S. Cytron[2], *A. Paz[2],I. Koziol[3], R. Ghavamian[4], D. Jocham[5], E. Gez[6], T. Torre[7], M. Bassignani[7], S. Kalnicki[8], M. Garg[8], G. Kovacs[9] , M. Anscher[10], F. Zattoni[1], G. Scarzello[11] .*

[1]Padova University Hospital, Urology Padova, Italy; [2]Barzilai Medical Center, Urology, Ashkelon, Israel; [3]VA Urology, Urology, Richmond, VA, USA; [4]Montefiore Medical Center, Urology, New York City, NY, USA [5]University Hospital Schleswig-Holstein, Urology, Lübeck, Germany; [6]TASMC, Radiotherapy, Tel Aviv, Israel; [7]VA Urology, Radiotherapy, Richmond, VA, USA; [8]Montefiore Medical Center, Radiotherapy, New York City, NY, USA; [9]University Hospital Schleswig-Holstein, Radiotherapy, Lübeck, Germany; [10]Virginia Commonwealth University, Radiotherapy, Richmond, VA, USA; [11]Padova University Hospital, Radiotherapy, Padova, Italy.

Purpose of Study

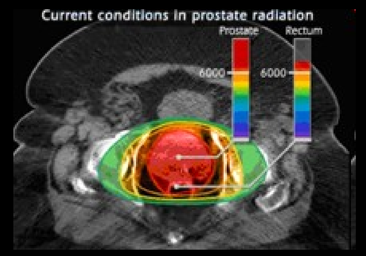
To report on the evaluation of the safety and efficacy of a novel inflatable bio-degradable balloon device. The device is transperineally inserted between the prostate and rectal wall prior to prostate radiotherapy to create a protective space and achieve rectal separation, resulting in lower rectal doses during external beam radiation treatment.

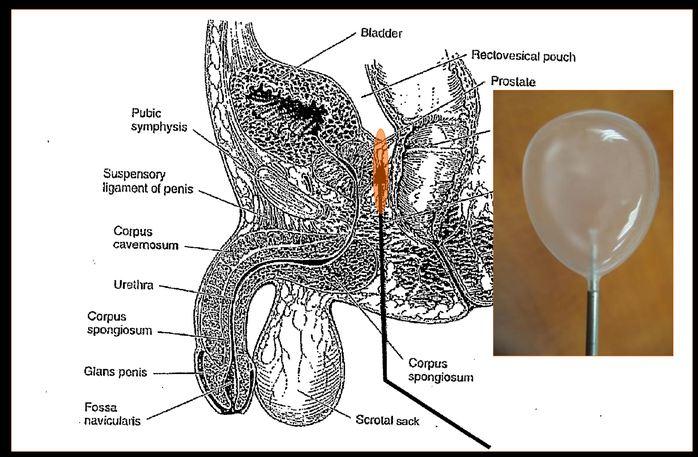
Materials and Methods

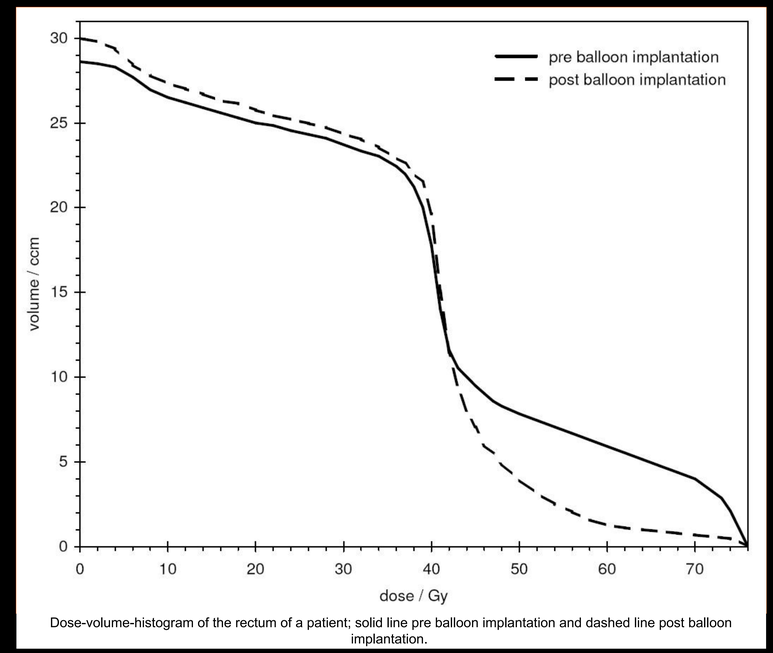
24 subjects scheduled for external beam radiotherapy were enrolled from June 19th 2009 to August 6th 2010 for this multi-center prospective study BPI-01 to undergo placement of the balloon device prior to initiation of treatment. This study followed an earlier single center feasibility study with 7 subjects in Israel that established the proper balloon insertion technique. The balloon is designed to degrade in situ after 3-6 months from time of placement. Placement was performed under transrectal ultrasound (TRUS) guidance while the subject is in the lithotomy position and under either local or general anesthesia (hospital and subject's choice). Once the dedicated needle is positioned and visualized in the space between the prostate and rectal fascia, it is advances slowly while injecting 5-10cc of saline under TRUS control for hydrodissection and delineation of the area between the prostate and rectal fascia until reaching its final position at the prostate base near the seminal vesicles. This step was followed by the insertion of an introducer and the balloon. Prior to balloon placement, baseline CT/MRI scans were obtained and compared to post-balloon placement scans. Additional weekly CT or US scans were performed during XRT to demonstrate balloon stability, and at 3 and 6 months after balloon implantation to demonstrate subsequent self-degradation of the device. The study follow-up was 6 months post implantation.
Data on side effects and device/procedure adverse events as well as radiation side effects was collected. The calculated endpoints of the study were safety (based on incidence of balloon-related adverse events) and efficacy (% reduction of radiation to the rectum at V50Gy, V60Gy, D100, D90, D70 and D50).

Results

In all cases the balloon was placed in midline between the prostate and the rectum without complications. The last 5 cases required 10-15 minutes and were performed with local anesthesia only. Only 3 patients that were implanted using general anesthesia had urinary retention and the catheter was removed after a few hours. In next cases the catheter was prophylactic inserted. Pain level was mild and only for a few hours after procedure. No acute proctitis over Grade 1 was observed during and following XRT and up to 3 months (all 24 patients) and 6 months follow-up (median), which was significantly lower than an average of 35% acute proctitis rate in the literature. The median balloon measurements in situ were: A-P - 19.2 mm (ranged 14.6 - 23.4), width - 30.5 mm (21.1 - 36.6) and cranio-caudal - 45mm. These separations resulted in an **average reduction of 69.9% of the volume of rectum receiving 90% of prostate prescribed dose**. Weekly follow up demonstrated stable separation and no change in balloon position and shape in all cases. In 3 cases the balloon deflated prematurely due to contact with fiducial markers introduced transrectally. No premature deflation occurred in cases where the markers were inserted transperineally. The balloons degraded as planned within 3-6 months.







Dose-volume-histogram of the rectum of a patient; solid line pre balloon implantation and dashed line post balloon implantation.

Fig. 1 below shows axial anatomical MRI images of the pre implantation (1a) and post implantation (1b) balloon located between the prostate and the balloon measurements in subject GER0102.

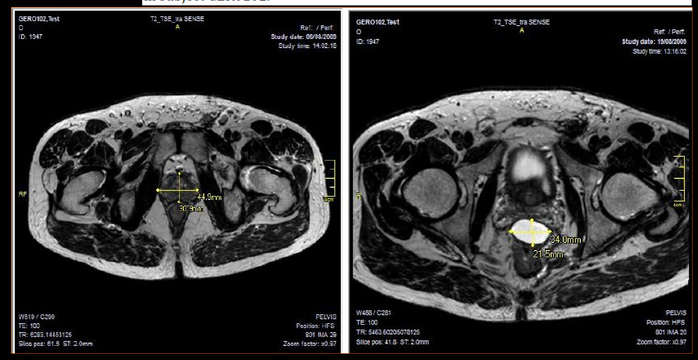


Fig. 2 below shows pre- and post-implantation DVH for subject GER0102 (same subject of Fig 1). **Red** arrow pointing pre-implantation rectum DVH and **green** arrow pointing post-implantation rectum DVH.

Discussion and Conclusions

Insertion of the balloon transperinealy under TRUS guidance proved to be a safe and fast procedure , feasible under local anesthesia. The balloon presence resulted in a stable separation of the prostate from the rectum and a the radiation dose to it and it also resulted in significant reduction of acute toxicity to the rectum.