



What do these results mean for individuals with high-risk localized or locally advanced prostate cancer?

- Adding apalutamide + ADT before and after prostate surgery improved outcomes compared with prostate surgery alone for enrolled patients. The treatment reduced the risk of the cancer either spreading or returning, or death



Why was this study done?

- Researchers from the original PROTEUS study wanted to carry out a sub-study to find out whether adding apalutamide and hormone therapy (ADT) before and after prostate surgery could improve outcomes for patients compared with surgery alone

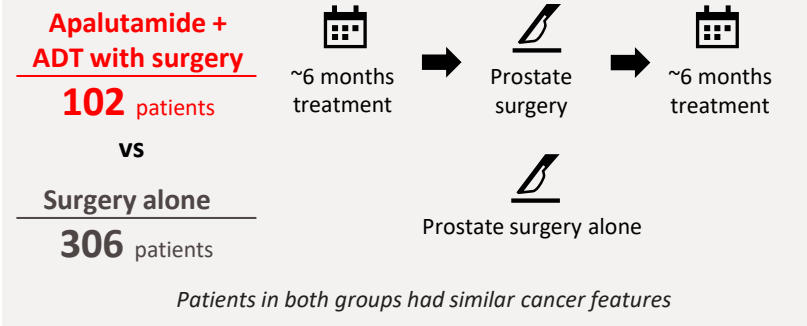


Who took part and what treatment did they receive?

- A total of 408 patients took part in the PROTEUS sub-study (NCT03767244). Each patient was randomly assigned in a 1:3 ratio to receive either apalutamide + ADT alongside surgery or surgery alone
- Apalutamide + ADT was given for ~6 months before prostate surgery (to shrink the tumor before surgery) and ~6 months after surgery (to help prevent the cancer from returning). Both groups underwent the same standard surgery: radical prostatectomy and pelvic lymph node dissection



Patients diagnosed with prostate cancer only in the prostate or nearby area without it having spread to other parts of the body were included



Primary objectives:

- To estimate the length of time patients lived without experiencing certain events showing that their cancer had returned or worsened

Other key secondary objectives:

- How long patients lived without their cancer spreading to other parts of the body
- How long patients went before needing another treatment for their prostate cancer



37.8 months

Median time patients continued study follow-up after enrollment

Perioperative apalutamide plus ADT and surgery in high-risk localized or locally advanced prostate cancer: a PROTEUS sub-study

Alberto Briganti¹, Thomas Steuber², Neal D Shore³, Martin Gleave⁴, Alexander Kretschmer⁵, Lisa Wetherhold⁵, Eleni Efstathiou⁶, David J Cahn⁷, Ronaldo Damião⁸, Alexandre De La Taille⁹, Boris A Hadaschik¹⁰, Bernardo Herrera Imbroda¹¹, Álvaro Juárez Soto¹², Giuseppe Simone¹³, Zhuokai Li¹⁴, Sharon A McCarthy¹⁵, Mark Wildgust¹⁶, Suneel D Mundle¹⁶, Adam S Kibel¹⁷, Mary-Ellen Taplin¹⁸

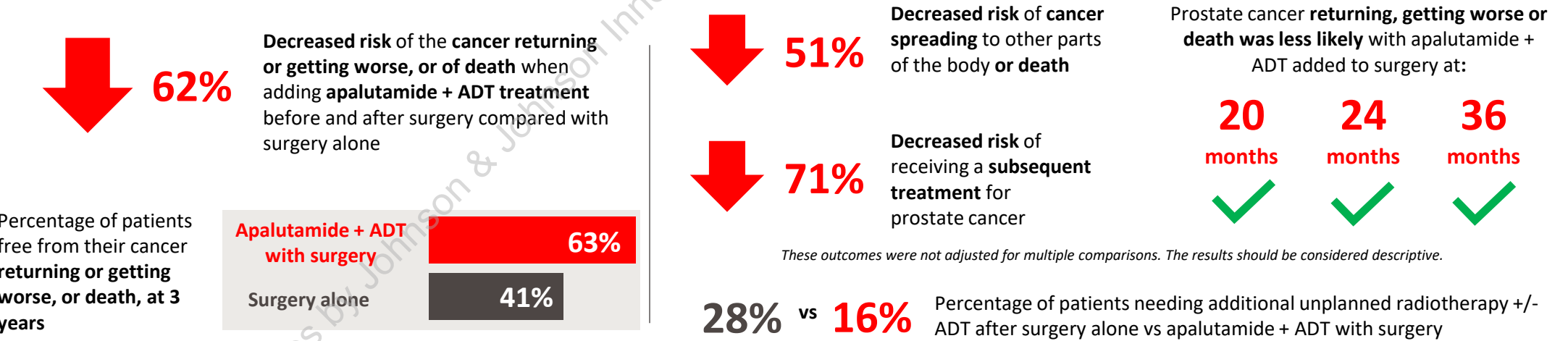
¹Division of Experimental Oncology/Unit of Urology, Urological Research Institute (URI), Comprehensive Cancer Center, IRCCS Ospedale San Raffaele, Vita-Salute San Raffaele University, Milan, Italy; ²Martini-Klinik Prostate Cancer Center, University Hospital Hamburg-Eppendorf, Hamburg, Germany; ³Urology, START Carolinas/Carolina Urologic Research Center, Myrtle Beach, SC, USA; ⁴Department of Urologic Sciences, University of British Columbia, Vancouver, BC, Canada; ⁵Innovative Medicine R&D Oncology, Johnson & Johnson, Spring House, PA, USA; ⁶Department of Genitourinary Medical Oncology, Knight Cancer Institute, Oregon Health and Science University, Portland, OR, USA; ⁷Colorado Clinical Research, Colorado Urology, Lakewood, CO, USA; ⁸Department of Surgery (Urology), Universidade do Estado do Rio de Janeiro, Rio de Janeiro; ⁹Department of Urology, Centre Hospitalier Universitaire Henri Mondor, Créteil, France; ¹⁰Department of Urology, University of Duisburg-Essen and German Cancer Consortium (DKTK)-University Hospital Essen, Essen, Germany; ¹¹Urology Department, Hospital Universitario Virgen de la Victoria, IBIMA-Plataforma BIONAND, Málaga, Spain; ¹²Urology Department, Hospital Universitario de Jerez de la Frontera, Cadiz, Spain; ¹³Department of Urology, IRCCS Regina Elena National Cancer Institute, Rome, Italy; ¹⁴Statistics & Decision Science SH, Johnson & Johnson, Shanghai, China; ¹⁵Clinical Research Oncology, Johnson & Johnson, Spring House, PA, USA; ¹⁶Global Medical Affairs, Johnson & Johnson, Raritan, NJ, USA; ¹⁷Department of Urology, Mass General Brigham and Harvard Medical School, Boston, MA, USA; ¹⁸Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, Boston, MA, USA



What were the results?

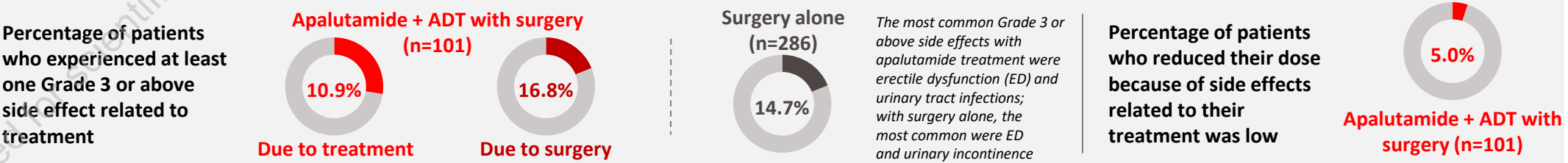
Treatment with apalutamide + ADT before and after surgery improved cancer outcomes and decreased the risk of needing subsequent treatment for prostate cancer

These results suggest that adding apalutamide + ADT before and after surgery helps to optimize the cancer outcomes of surgery



Side effects with apalutamide + ADT were consistent with those observed in previous studies and the main PROTEUS study

Percentage of patients experiencing Grade 3 or above side effects were similar in both groups; most were related to surgery rather than treatment



Glossary of terms

ADT	Androgen deprivation therapy, a treatment that lowers male hormones (like testosterone) to slow or stop prostate cancer growth.	Grade	A grading system from 1 to 5 used to describe the severity of a side effect. Side effects graded 1 or 2 are considered mild to moderate. Side effects graded 3 or above are considered serious and need immediate medical attention.	Localized prostate cancer	Prostate cancer that is only located inside the prostate and has not spread to other parts of the body.
Locally advanced prostate cancer	Prostate cancer that has spread only to a nearby area but not to distant parts of the body.	Pelvic lymph node dissection	A surgery that is performed to remove lymph nodes near the prostate as a preventative measure to stop the cancer spreading.	Radical prostatectomy	A surgery to remove the entire prostate gland and some of the surrounding tissue that is a standard treatment for prostate cancer.