Impact of a Rash Management Guide on Incidence and Severity of Rash with Apalutamide: Experience from the Apa-RP Study in High-risk Localized Prostate Cancer

Neal Shore,[1] Jason Hafron,[2] Daniel Saltzstein,[3] Amitabha Bhaumik,[4] Pankaj Aggarwal,[5] Rushikesh Potdar,[5] Jennifer Phillips,[5] Tracy McGowan[5]

[1]Carolina Urologic Research Center, Myrtle Beach, SC, USA; [2]Michigan Institute of Urology, West Bloomfield, MI, USA; [3]Urology San Antonio, San Antonio, TX, USA; [4]Janssen Research and Development, Titusville, NJ, USA; [5]Janssen Medical Affairs, Horsham, PA, USA

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KEY TAKEAWAY

By having healthcare teams follow a simple rash awareness algorithm, it may be possible to reduce the incidence, severity, and time to resolution of rash. Therefore, this may reduce the need to discontinue or lower the dose of apalutamide.

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AUTHOR'S CONCLUSIONS

- The Apa-RP rash management guide demonstrates a proactive and patient-empowered approach to monitoring and managing patients on apalutamide who develop skin rash.
- Patients in Apa-RP experienced lower overall incidence of rash, and for those who did experience rash, there was reduced severity, a shortened time to resolution, and lower rates of dose reduction and treatment interruption or discontinuation, vs those in SPARTAN and TITAN.
- Improvements in rash management in Apa-RP suggest that early identification and intervention may help to reduce the incidence, severity, and time to resolution of rash during treatment with apalutamide.

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BACKGROUND

- Apalutamide is an androgen receptor signaling inhibitor approved for patients with nonmetastatic castration-resistant and metastatic castration-sensitive prostate cancer[1] based on the SPARTAN (NCT01946204)[2] and TITAN (NCT02489318)[3] studies
  - The safety profile is similar across indications, with skin rash emerging as a common adverse reaction.
- In the subsequent Phase 2 Apa-RP study, a rash management guide was implemented to aim to improve dermatologic AEs.
- We present rash-related safety data from Apa-RP compared descriptively with data from SPARTAN
  and TITAN.

AE, adverse event.

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METHODS

- Apa-RP is a multicenter, open-label, single-arm Phase 2 study of adjuvant treatment with apalutamide and ADT in treatment-naïve patients with high-risk localized prostate cancer who underwent radical prostatectomy (NCT04523207)
  - Apa-RP included an exclusively US population recruited from 28 large-group urologic practices.
- A standardized questionnaire was utilized during scheduled phone calls to help patients quickly identify the onset of rash, take preventive measures, and immediately seek necessary medical attention
  - In Apa-RP, the pre-specified rash management guide (Figure 1) outlined proactive steps for medical management of rash, as well as educating patients on gentle skin care to reduce the onset and severity of rash events, including the use of light emollients and antiseptic-containing soap substitutes. Patients were advised to avoid harsh soaps, exposure to strong sun conditions, and hot baths, showers, and saunas.
- Rash incidence, severity, treatment, time to first onset, resolution, and time to resolution data were collected:
  - Rash occurrence was monitored, and skin-related AEs were defined by CTCAE v5.0 grading scale
  - Time to first onset of rash was defined as the number of days from first dose of the study drug to first rash
  - Time to resolution was defined as the number of days from the date of first rash to complete resolution of all rash
  - Rash was considered resolved on resolution of all skin lesions.
- Data from Apa-RP were compared descriptively with data from the North American populations of the global SPARTAN[2] and TITAN[3] studies.

ADT, androgen deprivation therapy; AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; US, United States.

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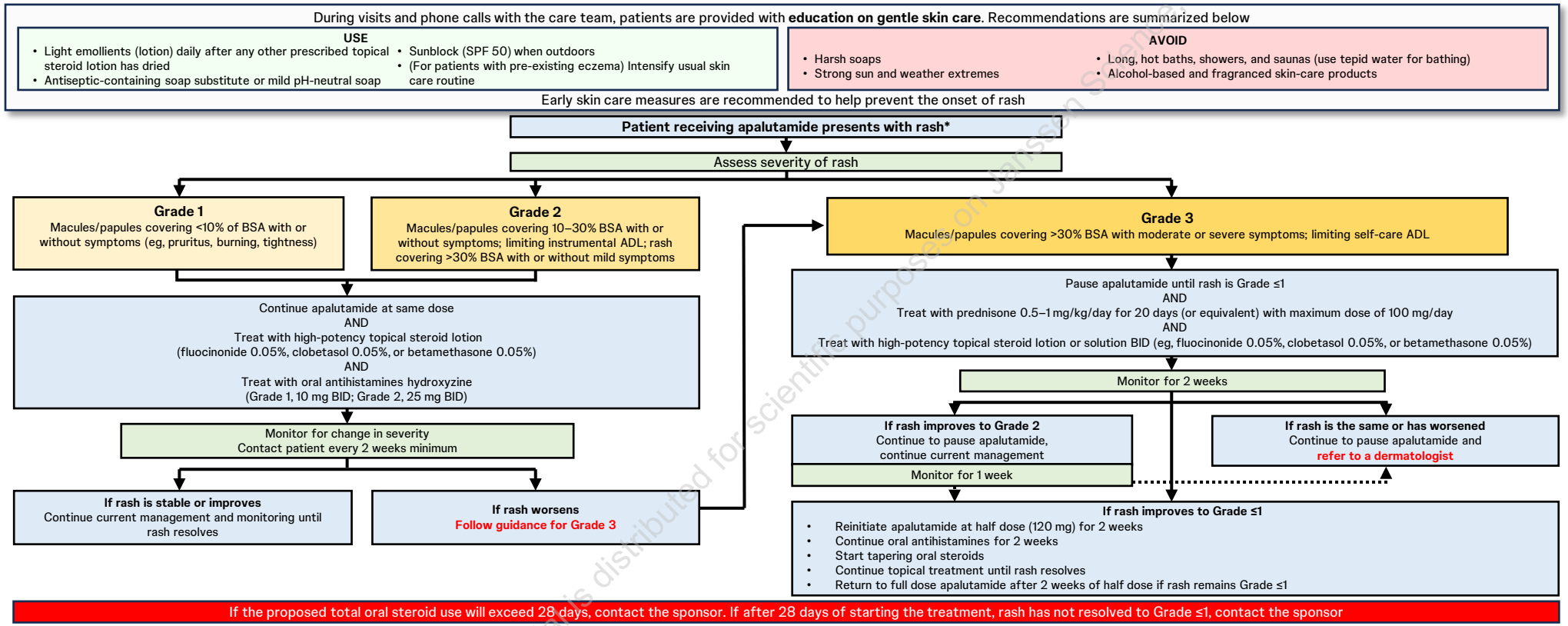
METHODS

FIGURE 1: Apa–RP dose modification and management guidelines for skin rash



*Rash is a grouped term that includes MedDRA Preferred Terms related to the general term 'rash'.
ADL, activities of daily living; BID, twice daily; BSA, body surface area; pH, potential of hydrogen; SPF, sun protection factor.

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RESULTS

Baseline characteristics

- All 108 patients enrolled in Apa-RP were treated with apalutamide 240 mg once daily for a maximum of 12 cycles (One cycle = 28 days)
  - Ninety-six patients received injectable ADT
  - Twelve patients received oral relugolix.

ADT, androgen deprivation therapy.

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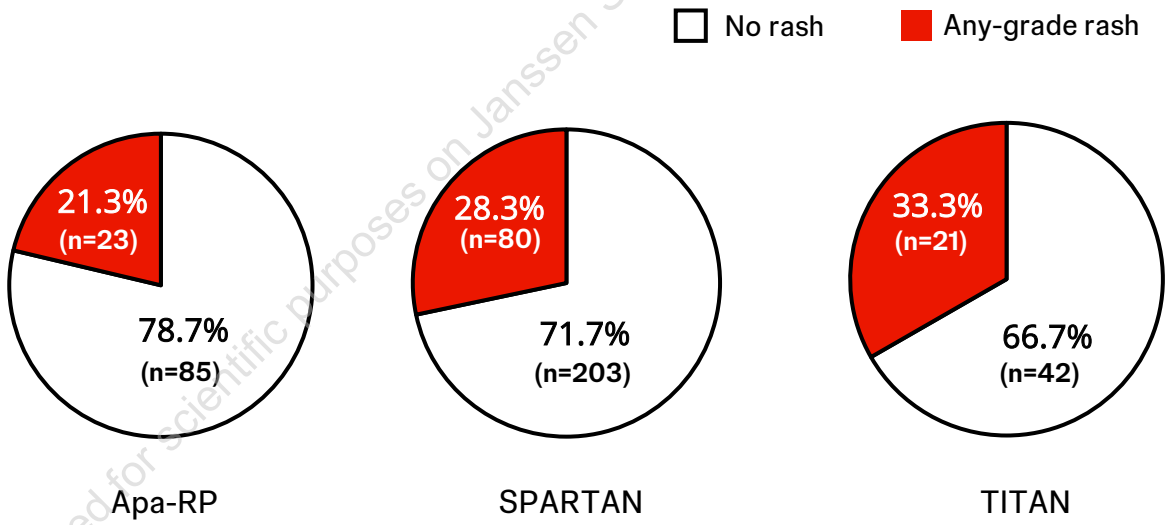
Rash incidence and severity

- Fewer patients experienced any-grade rash in Apa-RP vs those in the North American populations of SPARTAN and TITAN (21.3% vs 28.3% and 33.3%, respectively; Figure 2).

FIGURE 2: ANY-GRADE RASH INCIDENCE



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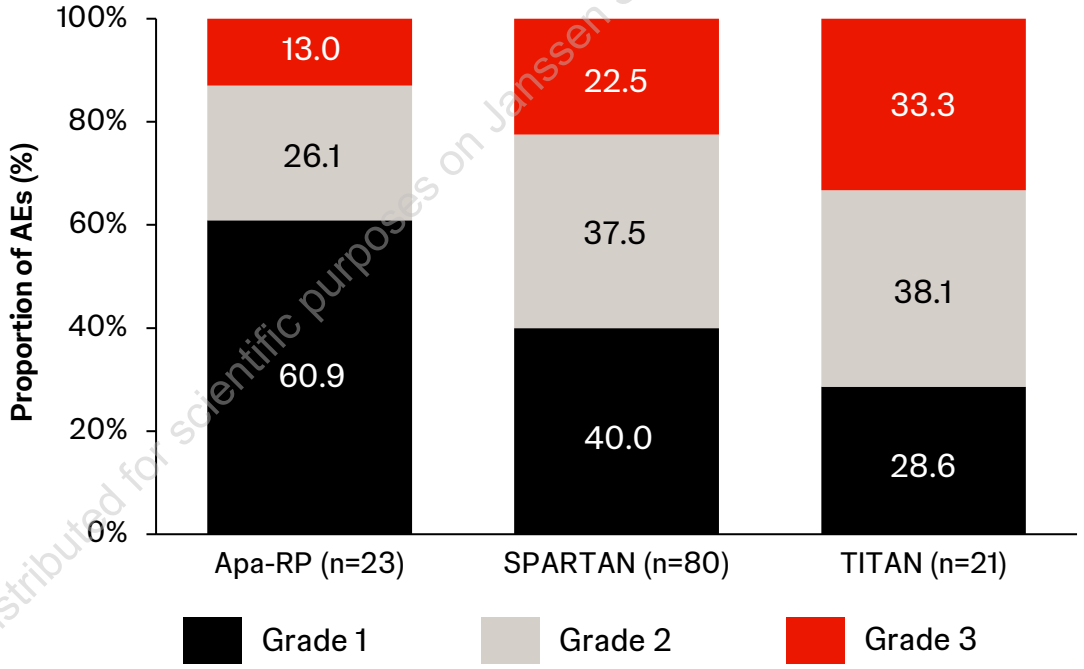
RESULTS

Rash incidence and severity

- Over 60.9% of rash events in Apa-RP were Grade 1, compared with 40.0% and 28.6% rash events in the North American populations of SPARTAN and TITAN (Figure 3).

FIGURE 3: PROPORTION OF RASH AEs BY GRADE



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Time to rash onset and resolution

- Median time to first report of rash was shorter in Apa-RP at 79.0 days, vs 97.5 days and 84.0 days in SPARTAN and TITAN, respectively.
- In Apa-RP, 22/23 events resolved (95.7%) while 75/80 (93.8%) and 12/21 (57.1%) resolved in SPARTAN and TITAN, respectively.
- Median time to rash resolution was also shorter in Apa-RP at 45.5 days, vs SPARTAN (60.0 days) and TITAN (142.0 days; Table 1).

Treatment interruptions and patterns

- The proportion of patients with any-grade rash who underwent dose reductions, treatment interruptions, or treatment discontinuations was lower in Apa-RP (4.3%, 26.0%, 0%), vs SPARTAN (10.0%, 23.8%, 6.3%) and TITAN (19.0%, 33.3%, 9.5%).
- The proportion of patients who developed rash and received systemic corticosteroids, topical corticosteroids, or oral antihistamines varied between the three studies.

TABLE 1: SIDE-BY-SIDE COMPARISON OF RASH-RELATED DATA FROM Apa-RP, SPARTAN, AND TITAN (NORTH AMERICAN SAFETY POPULATIONS)

	Apa-RP N=108	SPARTAN N=283	TITAN N=63
Time to rash onset and resolution, days			
Median time to onset of first skin rash*	79.0	97.5	84.0
Median time to resolution	45.5	60.0	142.0
Study treatment interruptions, n/N (%)†			
Dose reduction of study drug following onset of treatment-emergent rash	1/23 (4.3)	8/80 (10.0)	4/21 (19.0)
Treatment interruption following onset of treatment-emergent rash	6/23 (26.0)	19/80 (23.8)	7/21 (33.3)
Discontinuation of study drug following onset of treatment-emergent rash	0	5/80 (6.3)	2/21 (9.5)
Rash treatments, n/N (%)†			
Received any treatment for rash	11/23 (47.8)	36/80 (45.0)	11/21 (52.4)
Received topical corticosteroid	10/23 (43.5)	21/80 (26.3)	11/21 (52.4)
Received oral antihistamine	5/23 (21.7)	22/80 (27.5)	2/21 (9.5)
Received systemic corticosteroid	3/23 (13.0)	17/80 (21.3)	3/21 (14.3)

*Regardless of grade of first skin rash. The starting time for median calculation is the date of the first dose of the study drug. †Percentage is presented as proportion of patients with any grade rash.

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3. Chi KN, et al. *N Engl J Med.* 2019;381:13–24.

DISCLOSURES:

Neal Shore has been a consultant (honorarium only) for Janssen Pharmaceuticals

Jason Hafron has been a consultant and speaker for Janssen Pharmaceuticals

Daniel Saltzstein has been a consultant and speaker for Janssen Pharmaceuticals, and has received research funding from Janssen Pharmaceuticals

Amitabha Bhaumik, Pankaj Aggarwal, Rushikesh Potdar, Jennifer Phillips, and Tracy McGowan are employees of Johnson & Johnson Innovative Medicines

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