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Quality of Life in Men With Prostate Cancer Randomly Allocated to Receive Docetaxel or Abiraterone in the STAMPEDE Trial

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APPENDIX

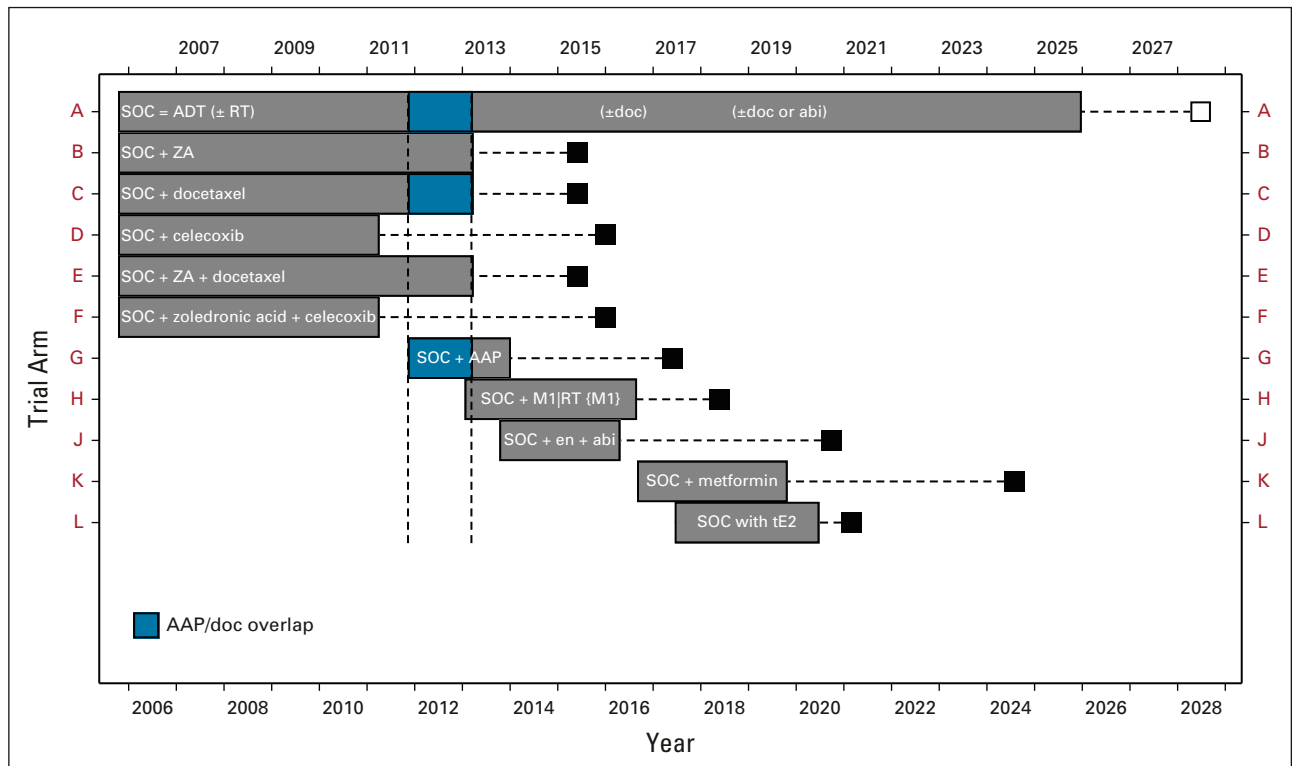


FIG A1. Activity by time in the STAMPEDE trial. Gray boxes represent periods of recruitment (x-axis) to each of the trial arms (y-axis). The black squares represent the timepoint of the first key comparative analysis for each trial arm. Patients included in this QOL analysis were randomly assigned during the period highlighted in blue; the primary analysis is between docetaxel + SOC and AAP + SOC, with SOC patients presented for context. AAP, abiraterone acetate plus prednisone or prednisolone; abi, abiraterone; doc, docetaxel; en, enzalutamide; M1, metastatic prostate cancer; QOL, quality of life; SABR, stereotactic ablative radiotherapy; SOC, standard of care; tE2, transdermal oestradiol; ZA, zoledronic acid.

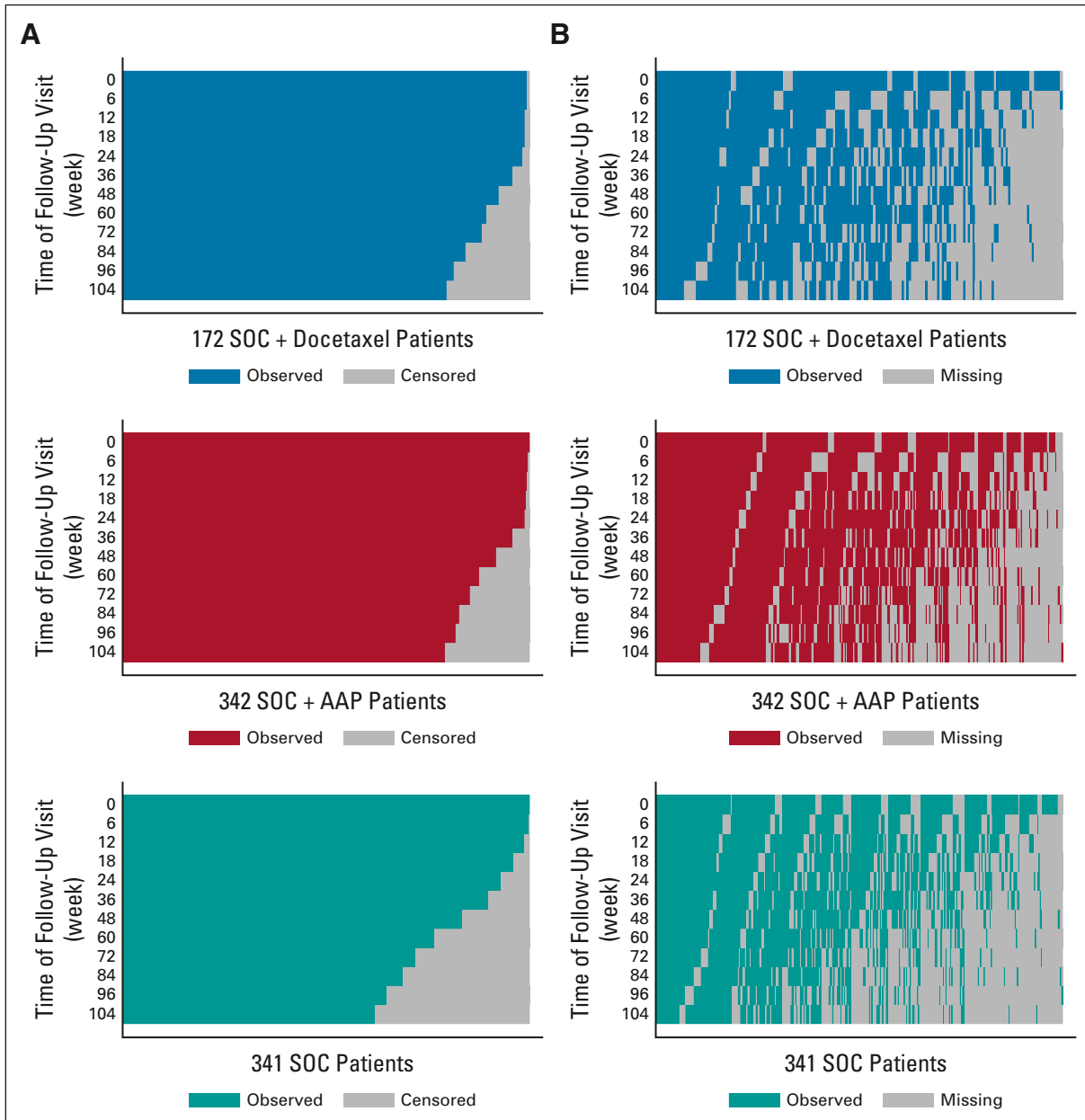


FIG A2. Patterns of missing patient data. (A) Censored data presented per allocated treatment. Each row represents a follow-up appointment where we would expect the patient to complete a QOL questionnaire. Each column represents a patient. A solid color indicates the patient was considered in this analysis. Gray means the patient was censored for starting second-line treatment or death and any data received did not contribute to the analysis. (B) Missing data presented by allocated treatment. Each row represents a follow-up appointment where we would expect the patient to complete a QOL questionnaire. Each column represents a patient. A solid color indicates the patient provided a QOL questionnaire at this timepoint. Gray means there was no QOL questionnaire received and reflects missing data from the analysis. AAP, abiraterone acetate plus prednisolone or prednisone; QOL, quality of life.

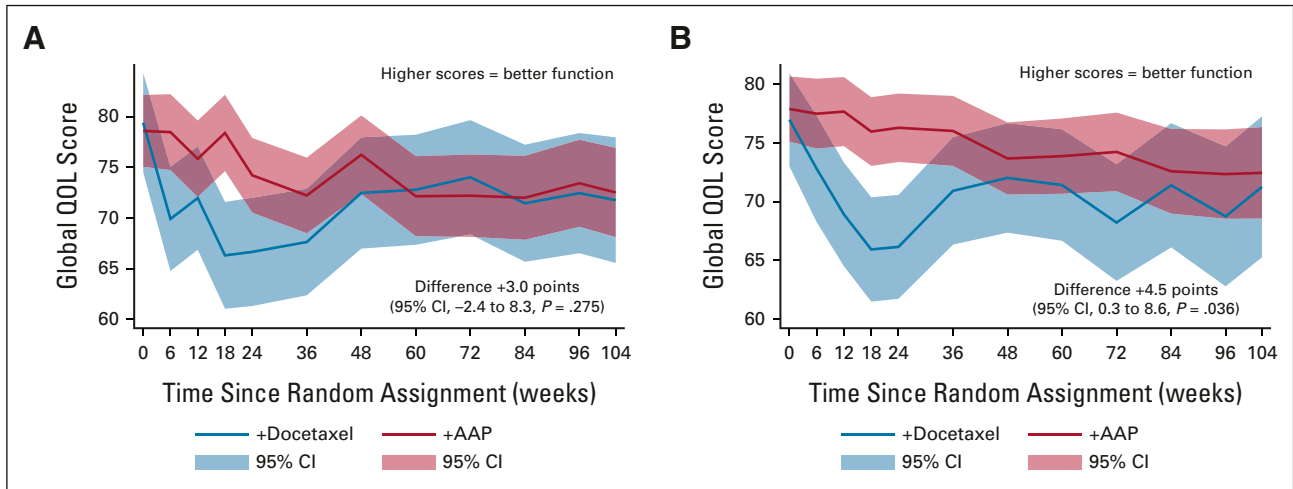


FIG A3. Longitudinal analysis showing global-QOL score over the first 2 years in patients with nonmetastatic disease and metastatic disease, separating scores for patients treated with docetaxel + SOC versus AAP + SOC. The difference is calculated by subtracting the docetaxel + SOC score from the AAP + SOC score; a positive difference represents a higher QOL for patients treated with AAP + SOC and a negative difference indicates a higher QOL for patients receiving docetaxel + SOC. Higher scores indicate better QOL. All scores are corrected as per QLQ-C30 guidelines to range from 0 to 100: (A) nonmetastatic disease and (B) metastatic disease. AAP, abiraterone acetate plus prednisone or prednisolone; QOL, quality of life; SOC, standard of care.

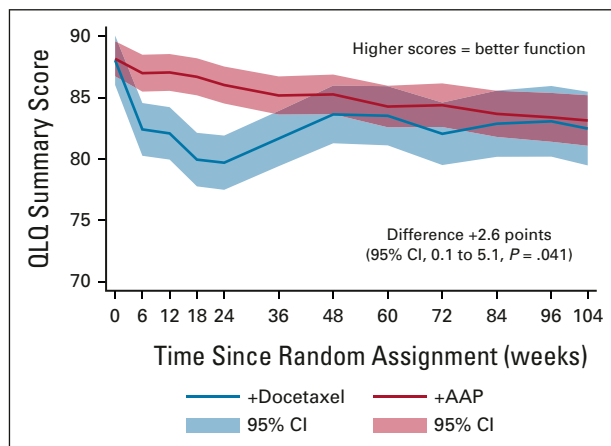


FIG A4. Longitudinal analysis showing the QLQ-C30 summary score over the first 2 years, separating scores for patients treated with docetaxel + SOC versus AAP + SOC. The difference is calculated by subtracting the docetaxel + SOC score from the AAP + SOC score; a positive difference represents a higher QOL for patients treated with AAP + SOC and a negative difference indicates a higher QOL for patients receiving docetaxel + SOC. Higher scores indicate better quality of life. All scores are corrected as per QLQ-C30 guidelines to range from 0 to 100. AAP, abiraterone acetate plus prednisone or prednisolone; QOL, quality of life; SOC, standard of care.

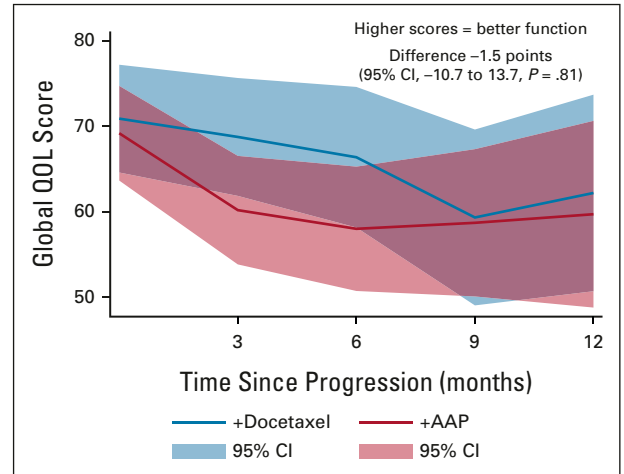


FIG A5. Longitudinal analysis showing the global-QOL score that occurred after progression, separating scores for patients treated in the upfront setting with docetaxel + SOC and AAP + SOC (ie, postprogression patients are potentially now receiving a different subsequent treatment). The difference is calculated by subtracting the docetaxel + SOC score from the AAP + SOC score; thus, positive a difference represents a higher QOL for patients treated with AAP + SOC and a negative difference indicates a higher QOL for patients treated with docetaxel + SOC. Higher scores indicate better quality of life. All scores are corrected as per QLQ-C30 guidelines to range from 0 to 100. AAP, abiraterone acetate plus prednisone or prednisolone; QOL, quality of life; SOC, standard of care.

TABLE A1. Suggested Boundaries for Determining Magnitude of Difference in QOL Scores and Whether a Difference is Clinically Meaningful: Small, Moderate, and Large Differences Are all Considered Potentially Clinically Meaningful

Boundary	Trivial	Small	Moderate	Large
Global-QOL	0-4	4-10	10-15	> 15
Physical functioning	0-5	5-14	14-22	> 22
Social functioning	0-5	5-11	11-15	> 15
Role functioning	0-6	6-19	19-29	> 29
Cognitive functioning	0-3	3-9	9-14	> 14
Pain	0-6	6-13	13-19	> 19
Fatigue	0-5	5-13	13-19	> 19

NOTE. This table has been adapted from Cocks et al.¹⁵

Abbreviation: QOL, quality of life.

TABLE A2. Proportion of Missing QOL Data at Each Timepoint for Patients in Treated With SOC, Docetaxel + SOC, and AAP + SOC

Week	SOC			Docetaxel + SOC			AAP + SOC		
	Received	Expected	%	Received	Expected	%	Received	Expected	%
0	283	341	83	153	171	89	303	342	89
6	235	340	69	112	171	65	239	341	70
12	245	336	73	116	170	68	249	340	73
18	226	327	69	109	170	64	248	339	73
24	226	317	71	108	169	64	265	338	78
36	223	306	73	109	165	66	253	328	77
48	204	284	72	106	159	67	241	314	77
60	183	261	70	111	154	72	229	300	76
72	164	245	67	103	152	68	216	292	74
84	157	235	67	95	145	66	198	283	70
96	132	221	60	82	140	59	185	280	66
104	134	211	64	79	137	58	183	271	68
Total	2,412	3,424	70	1,283	1,903	67	2,809	3,768	75

NOTE. The expected denominator reflects all patients who had not been censored (patients were censored at start of second-line treatment or death) at each timepoint. Received is the number of QOL questionnaires received at each timepoint.

Abbreviations: AAP, abiraterone acetate plus prednisone or prednisolone; QOL, quality of life; SOC, standard of care.