Quality of Life After Definitive Linac Stereotactic Radiotherapy for Prostate Cancer: Longitudinal Study

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Research Article

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Abstract

Prostate cancer represents the second most common malignancy in the world and majority of patients have diagnosis of localized disease. We examined quality of life after stereotactic body radiation therapy (SBRT) for prostate cancer. We included patients treated between 2016 and 2020. Inclusion criteria were: adenocarcinoma of the prostate; class risks low, intermediate, and high; WHO performance status 0-2. QoL was measured using the Functional Assessment of Cancer Therapy - Prostate (FACT-P). 439 patients were included, treated with SBRT. Median age was 73. Median follow-up was 34 months. FACT P-TOI ($p < 0.0001$), FACT G Total ($p = 0.0003$), and FACT P-total ($p < 0.0001$) declined at 1 month after the last SBRT, then recovered, and returned to the same level as before treatment at 3-4 month. The decrease in QoL at the first month was particularly remarkable in patients who received long-term hormone injections (36% patients). One month after the end of SBRT, about 22% patients were "quite a bit" or more in trouble with any side effect. We showed the longitudinal changes of quality of life by FACT-P after SBRT for prostate cancer. Prostate SBRT appears to be overall well tolerated.

Introduction

Prostate cancer (PC) represents the second most common malignancy in the world and the majority of PC patients have diagnosis of localized disease (1). There are multiple, efficacious guideline-recommended treatment options for localized PC, including radical prostatectomy, external beam radiation, and brachytherapy. A recent American Society for Radiation Oncology/American Society of Clinical Oncology/ American Urological Association (ASTRO/ASCO/AUA) guideline (2) included recommendations regarding use of stereotactic body radiotherapy (SBRT) for PC. According to the National Comprehensive Cancer Network (NCCN) Guideline Ver1. 2021 (3), 7.25-8 Gy * 5 radical SBRT for PC is indicated for low-risk to high- and ultra-high-risk cases. There is increasing awareness that quality of life alongside objective measures of late adverse genitourinary and gastrointestinal toxicity are essential to this decision-making process in the management of patients with PC. To the best of our knowledge, there have been no reports of evaluation of quality of life (QoL) fluctuations after radical prostate SBRT using the Functional Assessment of Cancer Therapy-Prostate (FACT-P) so far. The present study investigated long-term QoL of patients after SBRT using a valid and self-administered QoL questionnaire of FACT-P.

Materials And Methods

We conducted a cohort prospective survey of patients affected by PC treated with SBRT at our institution (University of Tokyo Hospital). Inclusion criteria were: (1) histologically proven adenocarcinoma of the prostate; (2) NCCN class risks low, intermediate, or high; (3) World Health Organization (WHO) performance status 0–2. Exclusion criteria were: (1) lymph node metastasis; (2) bone metastasis; (3) castration-resistant prostate cancer; (5) after radical prostatectomy; (6) SBRT for local recurrence after external beam radiation therapy; (7) local recurrence after high-intensity focused ultrasound (HIFU); (8)

not 5 fractionations. We didn't put a limit on prostate volume nor baseline International Prostate Symptom Score (IPSS) in order to include patients.

Combination hormone therapy

Basically, short-term hormones of 4–6 months were used in the medium-risk unfavorable group, and 1.5-2 years of hormone therapy were used in the high-risk group. There was no concomitant use of Bicalutamide, and the first Degarelix injection and the second and subsequent Leuprorelin injections. SBRT was performed when prostate-specific antigen (PSA) dropped to near 1.0 mg/mL. However, SBRT was started by the second month in the short term and by half a year at the longest in the long-term administration group.

SBRT method

The irradiation dose was planning target volume (PTV) 95% prescription, 36.25 Gy in 5 fractions before July 2018 was 54% and 40 Gy in 5 fractions after that was 43%. SBRT was performed using volumetric modulated arc therapy (VMAT) with the use of flattening filter free beams using a linear accelerator with image-guidance. SBRT was performed 5 times every other day excluding weekends. There were many cases in which SpaceOAR was inserted before SBRT. See our past report (4) for spacer insertion, planning magnetic resonance imaging (MRI) and computed tomography (CT) scan for SBRT, and the definition of target volume and organs at risk. The patient was given Glycerin enema of 30 or 40 cc 2 hours before examination or SBRT. After that, the patients were asked to drink water and to store their urine for 2 hours. From 4 days before the examination to the last day of SBRT, the patients were encouraged to take Elobixibat Hydrate or Macrogol 4000 every day. SBRT dose constrains were shown in the Table 1.

Follow-up

Follow-up intervals were calculated from the date of last SBRT dose. Outpatient follow-up is conducted 1 month and 3–4 months after the end of SBRT, every 3 months until 2 years, and every 6 months after the 2nd year. We have asked patients to fill in a QoL questionnaire each follow-up time since May 2016. PSA is measured every time, and when it exceeds 2.0 ng/mL twice in a row, contrast-enhanced MRI and/or ^{18}F-fluorodeoxyglucose (FDG) positron emission tomography (PET) examination is added to check for recurrence. When treatment such as chemotherapy was started for other double cancers, it was excluded from the questionnaire survey.

Statistical analysis

The risk classification was based on the NCCN risk classification v1. 2021 for PC. The paired t test was used for comparison of baseline. All P-values were two-sided, with $p < 0.05$ considered statistically significant. The FACT-P instrument (version 4) is a multidimensional, self-administered 39-item questionnaire. A FACT-P total score was obtained by adding emotional well-being (EWB), family well-being (FWB), physical well-being (PWB), social well-being (SWB) and prostate cancer subscale (PCS) (range 0-152), FACT-G (General) total score by adding EWB, FWB, PWB, SWB (range 0-104) and FACT-P

Trial Outcome Index (TOI) by adding FWB, PWB and PCS subscale scores (range 0-104) version 4 of the FACT scoring guidelines (5). Prorating was carried out only if more than 50% of the items on each subscale were answered. For all scales, the higher the score was, the better the QOL was. This study was approved by the institutional review board of Tokyo University (No. 3372-6). All methods were carried out in accordance with relevant guidelines and regulations. Informed consent was obtained from all subjects.

Results

Baseline patient characteristics are shown in Table 2. Median follow-up was 34 months (maximum: 54 months). Between May 2016 and Dec 2020, 439 patients answered the FACT-QoL questionnaire at some point. These 439 patients were all that had been treated with SBRT for prostate cancer with a curative intent in our institution during this period. The median age was 73 years, the median PSA before all treatments was 9.2 ng/mL, clinical T2a was the highest at 47%, and Gleason Score Group by NCCN was 28% and 27% for Group 2 and 3, respectively. The NCCN medium risk was 53% and high risk was also included at 42%. Short-term hormone combination for 4–6 months was 42% and long-term hormone combination was 36%. 177 patients (40%) had hydrogel spacer inserted between the prostate and rectum before SBRT.

The cumulative total number of patients who were caught in exclusion criteria during the same period was: SBRT for (1) lymph node metastasis in 12 patients; (2) bone metastasis in 11 patients; (3) castration-resistant prostate cancer in seven patients; (5) after radical prostatectomy in one patient; (6) local recurrence after external beam radiation therapy in two patients; (7) local recurrence after high-intensity focused ultrasound (HIFU) in three patients; (8) not 5 fractionations in one patient.

314 patients (71%) before SBRT, 242 patients (55%) at 1 month, 46 patients at 2 month, and 246 patients at 3 to 4 month, 197 patients at 5–7 month, 190 patients at 8–10 month, 165 patients at 11–13 month, 137 patients at 14–16 month, 117 patients at 17–19 month, 102 patients at 20–22 month, 85 patients at 23–25 month, 61 patients at 29–31 month, 50 patients at 32–34 month, 54 patients at 35–37 month, 44 patients at 38–42 month, 38 patients at 43–54 month, 29 patients at 43–48 month, 9 patients at 49–54 month filled out the questionnaire. Since we included all patients received SBRT in this survey, approximate 30% of patients did not complete the questionnaire before treatment.

In all of FACT P-TOI, FACT G Total, and FACT P-total, the QoL score at 1 month after the end of SBRT was once significantly lower than the value before SBRT (Fig. 1). The average score for each QoL dropped from 78.84 (standard error: 0.77) before SBRT to 72.35 (1.02) at 1 month in FACT P-TOI ($p < 0.0001$ by t-test), from 79.91 (0.79) to 75.38 (0.96) in FACT G Total ($p = 0.0003$), and from 114.22 (1.05) to 105.78 (1.31) in FACT P-total ($p < 0.0001$), respectively. After that, an improvement trend was seen in the second month (the average score: 74.62 (SE: 2.57), 77.13 (2.09), and 107.88 (3.23), respectively). Furthermore, at 3–4 month, all of FACT P-TOI ($p = 0.0011$, the average score: 76.80 (SE: 0.88)), FACT G Total ($p = 0.0410$, 78.15 (0.94)), and FACT P-total ($p = 0.0029$, 111.19 (1.24)) improved significantly from the 1st month. In the subsequent course, there was basically no re-decrease in the plateau until the 49-54th months.

In the long-term hormone-administered group, the QOL reduction of FACT P-TOI (67.99) and FACT P-total (102.08) at 1 month was larger than that in the short-term administration group (administration period of 6 months or less) and the hormone-free group (Fig. 2). In the hormone-free group, the bottom of all QoL was 2 months instead of 1 month. With respect to use of hydrogel spacer, the score of FACT P-TOI, FACT G Total, and FACT P-total at 1 month was 71.35 (SE: 1.02), 74.41 (0.96), and 104.26 (1.31) without spacer versus 74.97 (1.76) ($p = 0.11$ by unpaired t-test), 77.94 (1.69) ($p = 0.10$), and 109.74 (2.28) ($p = 0.062$) with spacer, respectively. With respect to the SBRT dose, the score of FACT P-TOI, FACT G Total, and FACT P-total at 1 month was 72.58 (SE: 1.17), 75.22 (1.09), and 105.60 (1.46) after 36.25 Gy ($p = 0.33$ of 36.25 Gy versus 40 Gy, $p = 0.68$ of 36.25 Gy versus 42.5 Gy, and $p = 0.99$ of 40 Gy versus 42.5 Gy), and 71.77 (2.21), 76.05 (2.16), and 106.39 (3.02) ($p = 0.71$, 0.82, and 0.74) after 40 Gy, 71.85 (6.29), 74.15 (5.47), and 105.15 (7.88) ($p = 0.79$, 0.84, and 0.88) after 42.5 Gy, respectively.

P7 (I have difficulty urinating) (the average score: 3.25 before SBRT, 2.49 at 1 month, and 3.14 at 2 months) and BL2 (I urinate more frequently than usual) (2.58, 1.62, and 2.22) bottomed out one month after the end of SBRT (both $p < 0.0001$) (Fig. 3). Improvement was seen at 2 month and was fully recovered at 3–4 month. P6 (I have trouble moving my bowels) and P8 (My problems with urinating limit my activities) on restriction of activity by urine continued to decline until the second month and recovered at 3–4 month (Fig. 3).

The percentage of those who answered that they were suffering from side effects of GP5 (I am bothered by side effects of treatment) was also the highest at 22% in the first month after the end of SBRT from 8% at pre-SBRT, and dropped to 11% in the 3rd to 4th months (Fig. 4). After that, it gradually decreased over time. Including "somewhat", it changed from 15% before SBRT into 45% at 1st month, 32% at 2nd month, and 28% at 3–4 months.

Discussion

In this prospective study, we evaluated the QoL of 439 patients treated with SBRT for low, intermediate, and high risk PC. Most of the QoL evaluations using FACT-P after SBRT for PC so far are only after SBRT for metastatic PC (6–8). Since they did not irradiate the primary prostate lesion, it cannot be compared with the QoL after the radical SBRT this time. This time, using FACT-P questionnaire, it is highly novel to see the time-series changes in QoL after radical PC SBRT. In this report, QoL declined at 1 month after the last SBRT, then recovered, and returned to the same level as before treatment 3–4 months. The decrease in QoL at the first month was particularly remarkable in patients who received combined long-term hormone injections. One month after the last SBRT, about 22% of people were "quite a bit or very much" in trouble with any side effect. Since the QOL score of patient-reported side effects (i.e. P6, P7, P8, and BL2) was also declining at the same time this time, this QOL changes in chronological order would be for SBRT-induced acute toxicity, though we did not compare patient-reported outcome measures (PROMS) with toxicity assessment like common terminology criteria for adverse events (CTCAE). In this study, we can’t report data on correlation between physician- and patient-reported outcomes.

Chen et al. (6) treated 100 PC patients with 36.25 Gy in five fractions (7.25 Gy per fraction) with a median follow-up of 27 months. Biochemical disease-free survival was 99%, and no acute Grade 3–5 gastrointestinal (GI) or genitorurinary (GU) toxicity was recorded (6). According to Franzese C (10), acute rectal toxicity of moderate–severe grade is reported in 6% patients after SBRT. Grade 2–3 GI toxicity was reported in 2 (2%) patients after SBRT (10). Acute GU toxicity of grades 2 and 3 was 31% after SBRT (10). The evidence from the phase 3 trial (HYPO-RT-PC) (17) suggested higher patient-reported toxicity with ultra-hypofractionation of 6.1 Gy x 7 fractions. Grade 2 or worse acute toxicity estimates for ultra-hypofractionation were similar to standard fractionation, ranging from 4–24% for GI toxicity and 4–40% for GU toxicity (17). By contrast, the results from the randomized PACE-B trial (16) suggested that substantially shortening treatment courses with SBRT did not increase either GI or GU acute toxicity. Worst acute RTOG GI and GU toxic effect proportions of grade 2 or more were 43 (10%) and 96 (23%) of 415 patients after SBRT, respectively (16). In our study, 45% patients answered “somewhat” or more and 22% “quite a bit” or more in GP5 (I am bothered by side effects of treatment) at 1 month after the last SBRT. In general, patient-reported side effects are more frequent than doctor-judged side effects.

According to Franzese C (10), regarding the late setting, grades 2 and 3 rectal toxicity was 1% and 0% after SBRT. While GU side-effect of Grade 1 was 44%, grades 2 and 3 toxicity was 2% and 0% after SBRT (10). According to the review of Wang et al. (11), after SBRT for PC, most toxicities were grade 1–2 with a very low overall incidence of grade 3–5 toxicity (usually < 3%). According to Hwang et al. (12), after SBRT with periprostatic hydrogel spacer (SpaceOAR; Augmenix) for localized PC, no grade 3–5 GU or GI toxicity was recorded. New grade 2 GU toxicity (urgency or dysuria) was present in 30% of patients at 1 month and in 12% of patients at 1 year post-treatment and GI toxicity was limited to grade 1 (16%) during SBRT, although 4% of patients developed grade 2 during the first 4 weeks after SBRT (12). Periprostatic hydrogel placement followed by prostate SBRT may result in minimal GI toxicity. In our study, 10–30% and 0–13% of patients answered “somewhat” or more and “quite a bit” or more in GP5 after 3–4 month, respectively.

There were times when the number of questionnaires was small, such as the 2nd month and after the 38th month. Since the number of questionnaires was very small of 10.5% (46/439 patients) at 2 month, the statistical power might also be low. Since we included all patients treated with SBRT during this period, only 71% patients had a baseline assessment and 55% was evaluated at 1 month. In this way, our QOL assessments might have become a heterogeneous distribution.

With respect to the previous report of the QoL change after the conventional IMRT method, only reports of changes in QoL after the conventional IMRT method reported that the timing of the initial questionnaire was 3 months after irradiation and no decrease in QoL was observed (13–15). This time, in addition to before SBRT, we collected QoL data for the earlier time of the first and second months after SBRT, which is also highly novel. We compared our findings with the previous QOL data of patients treated using low dose rate (LDR) and high dose rate (HDR) Brachytherapy. According to Slevin F et al. (18), maximal deterioration in mean urinary ($p < 0.001$) and sexual summary scores using a validated expanded prostate cancer index composite (EPIC) questionnaire was noted 6 weeks after implant, with severe

urinary symptoms and moderate bowel/sexual symptoms after HDR brachytherapy. At 6 months, urinary and bowel QOL had improved to mild impairment, which then fully resolved at 10 months (18). According to Strom TJ et al. (19), after median follow-up of 32 months, HDR brachytherapy (27–28 Gy in two fractions) and IMRT (74–81 Gy in 37–45 fractions) patients had significantly less deterioration in their urinary HRQOL than LDR (145 Gy in one fraction) brachytherapy patients at 1 and 3 months after irradiation. The only significant decrease in bowel HRQOL between the groups was seen 18 months after treatment, at which point IMRT patients had a slight, but significant, deterioration in their bowel HRQOL compared with HDR and LDR brachytherapy patients (19). As with Brachytherapy, the dose was prescribed inhomogeneous in order to spare the urethra. The homogeneous dose distribution may affect patient in a different way than with a heterogeneous brachytherapy treatment plan.

According to the Georgetown University's report (6), which is the only one looking at the QoL one month after SBRT, a median baseline American Urological Association Symptom Score (AUA) symptom score of 8 significantly increased to 11 at 1 month ($p = 0.001$), however returned to baseline at 3 months ($p = 0.60$).

Conclusions

QoL declined at 1 month after the end of prostate SBRT, then recovered, and returned to the same level as before treatment 3–4 months after SBRT. The decrease in QoL at the first month was particularly remarkable in patients who received long-term hormone injections. One month after the end of SBRT, about 22% of people were "quite a bit or very much" in trouble with some side effects.

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Tables

Table 1. Dose constraint of 40 Gy in 5 fractions

Dose constraint		With SpaceOAR		Without SpaceOAR	
Prostate	Volume	Goal	Torelance	Goal	Torelance
Urethra	Max				
	Max				
PTV	V110%	< 0.5%	< 2%	< 0.5%	< 2%
	D99%	> 39.5 Gy	> 39.17 Gy	> 39.2 Gy	> 38.1 Gy
	Max	< 43.26 Gy	< 44.14 Gy	< 43.9 Gy	< 45.5 Gy
	Mean	< 41.16 Gy	< 41.71 Gy	< 41.5 Gy	< 42 Gy
Bladder	V40Gy	< 3.7%	< 6%	< 4.6%	< 6%
	V20Gy	< 22.8%	< 35%	< 27.4%	< 49%
	V40.83Gy	< 6.2cc	< 8cc	< 6.9cc	< 10cc
	Max	< 42.7 Gy	< 44.14 Gy	< 43.4 Gy	< 45 Gy
	Mean	< 11.92 Gy	< 16.55 Gy	< 13.7 Gy	< 20 Gy
Rectum		1 cm above and below the PTV			
	V40Gy	< 0.5%	< 1.5%	< 2.5%	< 4%
	V36Gy	< 2.5%	< 5.7%	< 8%	< 11%
	V32Gy	< 5%	< 10%	< 13%	< 17%
	V30Gy	< 6.8%	< 13%	< 16%	< 20%
	V20Gy	< 28.2%	< 34%	< 32%	< 39%
	Max	< 40.83 Gy	< 42.48 Gy	< 42.7 Gy	< 43.9 Gy
	Mean	< 16.88 Gy	< 18.21 Gy	< 17.4 Gy	< 19.6 Gy
Femoral head	Max	< 17.66 Gy	< 18.76 Gy	< 17.66 Gy	< 18.76 Gy
Sigmonid colon	V30Gy	< 0cc		<1cc	
Penile bulb	Max	< 40 Gy		< 40 Gy	
Small bowel	V30Gy	0cc	< 5cc	0cc	< 5cc

Table 2. Patient characteristics

Factors	N	%
Total	439	100
Age (years old)		
Median (range)	73 (33-92)	
Quartile	68 and 78	
iPSA (ng/mL)		
Median (range)	9.2 (1.6-24.0)	
Quartile	6.3 and 14.7	
Clinical T-stage		
T1c	84	19.1
T2a	208	47.4
T2b	20	4.6
T2c	61	13.9
T3a	46	10.5
T3b	14	3.2
T4	6	1.4
Gleason score group		
Group 1	46	10.5
Group 2	121	27.6
Group 3	117	26.7
Group 4	82	18.7
Group 5	73	16.6
Risk group		
Low	21	4.8
Intermediate-low	84	19.1
Intermediate-high	149	33.9
High	112	25.5
Ver-high	73	16.6
Hormonal therapy		
None	98	22.3
Short term	183	41.7
Long term	158	36.0
RT total dose		
36.25 Gy	239	54.4
40 Gy	187	42.6
42.5 Gy	13	3.0

Abbreviation: PSA = prostate-specific antigen, RT = radiation therapy

Figures

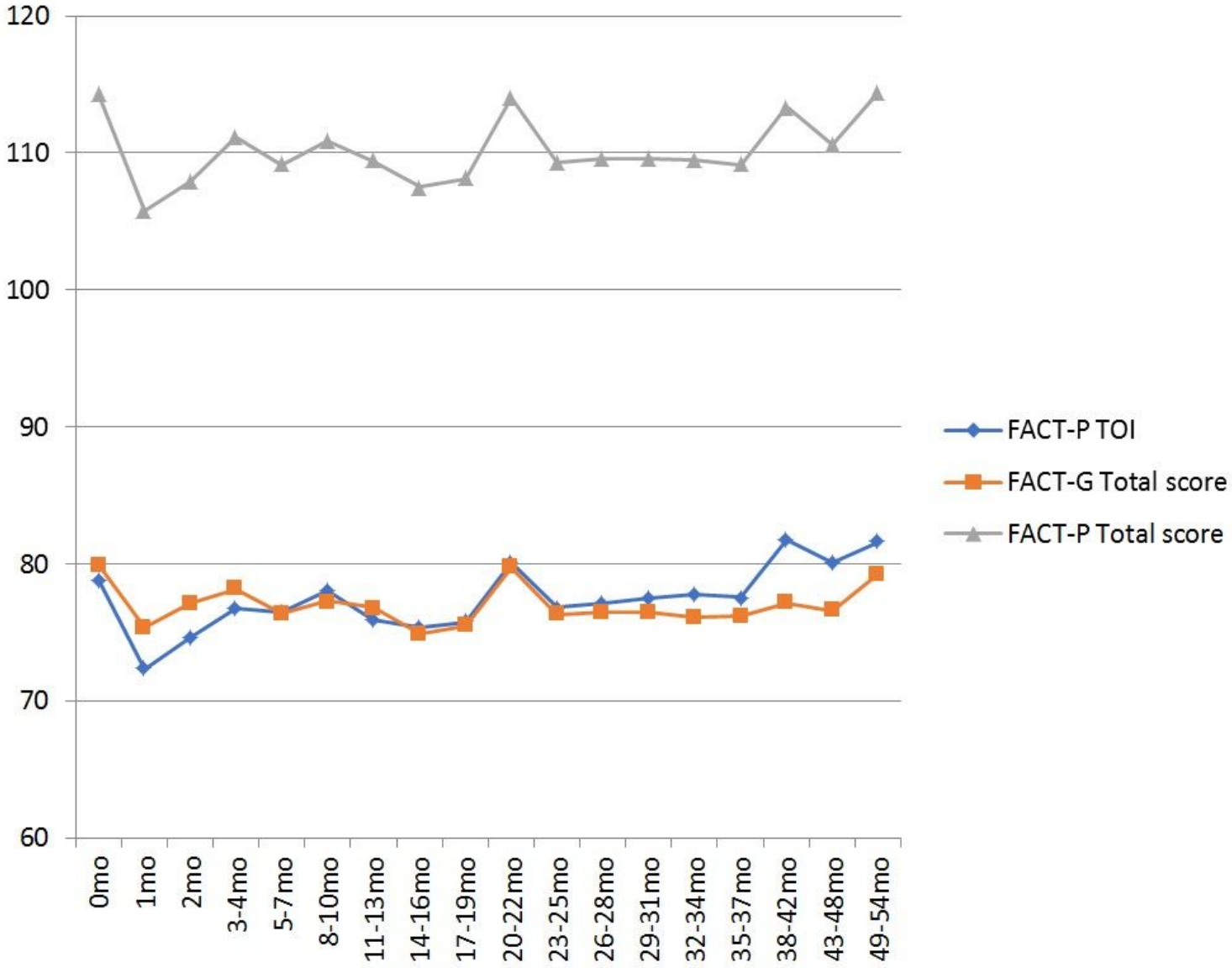

Figure 1

Mean Functional Assessment of Cancer Therapy-Prostate (FACT P) Trial Outcome Index score (TOI, blue line), Functional Assessment of Cancer Therapy-General (FACT G) Total score (orange line), and FACT P-total score (gray line) score. Time from last SBRT dose (months).

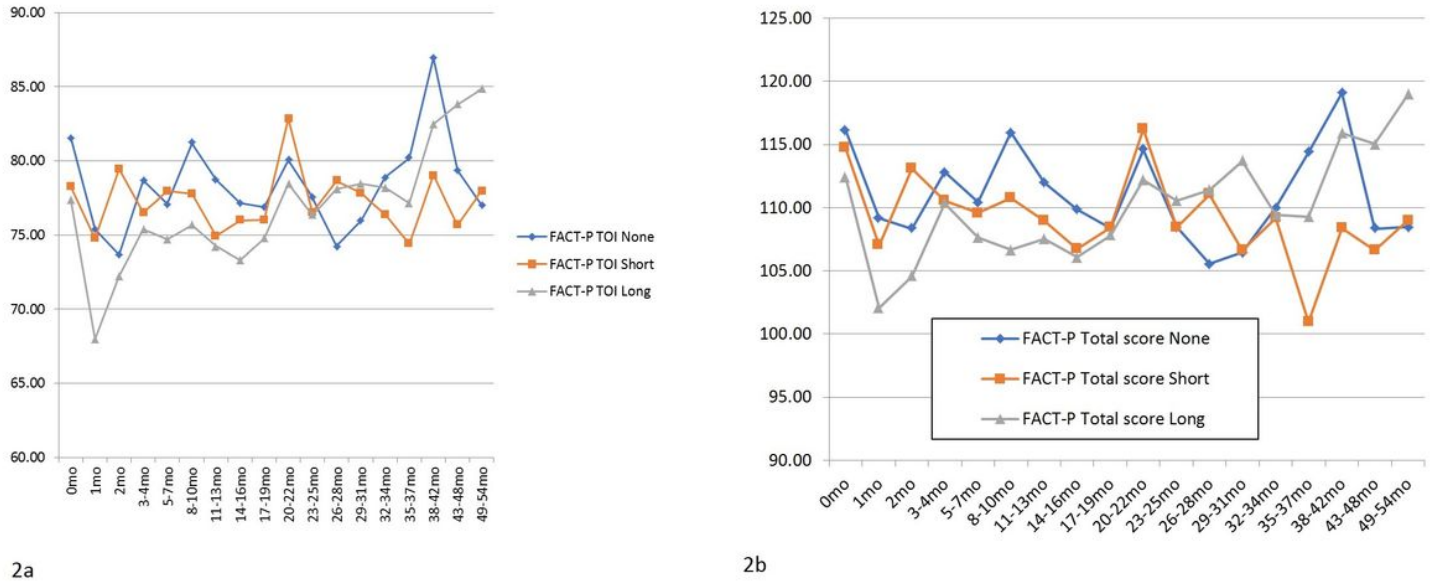

Figure 2

Mean Functional Assessment of Cancer Therapy-Prostate (FACT P) Trial Outcome Index (TOI) score (2-a) and mean FACT P-total score (2-b) by none (blue line), short term (orange line), and long term (gray line) hormonal therapy.

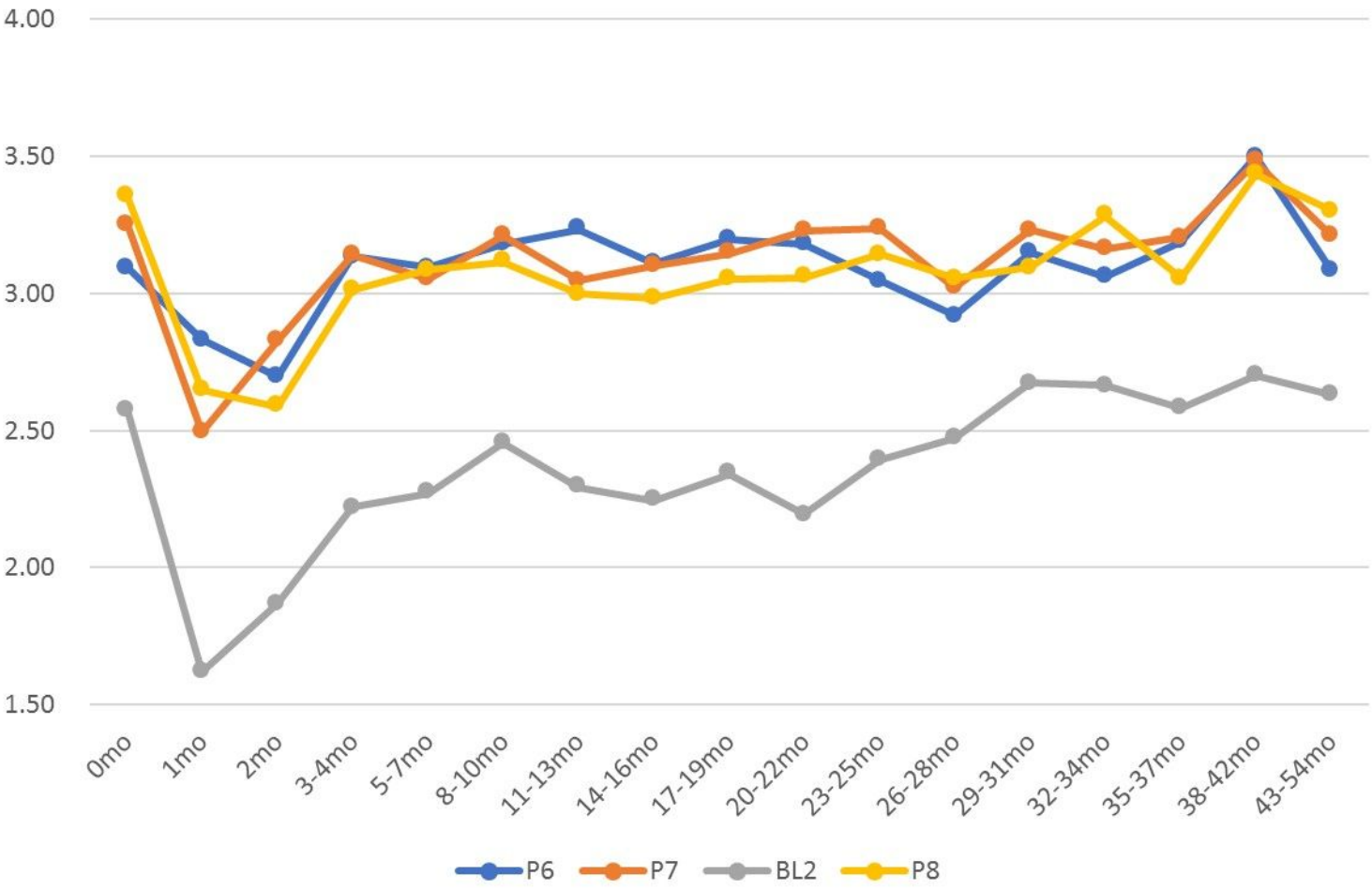

Figure 3

Mean four subscale scores. P6 (I have trouble moving my bowels): blue, P7 (I have difficulty urinating): orange, BL2 (I urinate more frequently than usual): gray, and P8 (My problems with urinating limit my activities): yellow line.

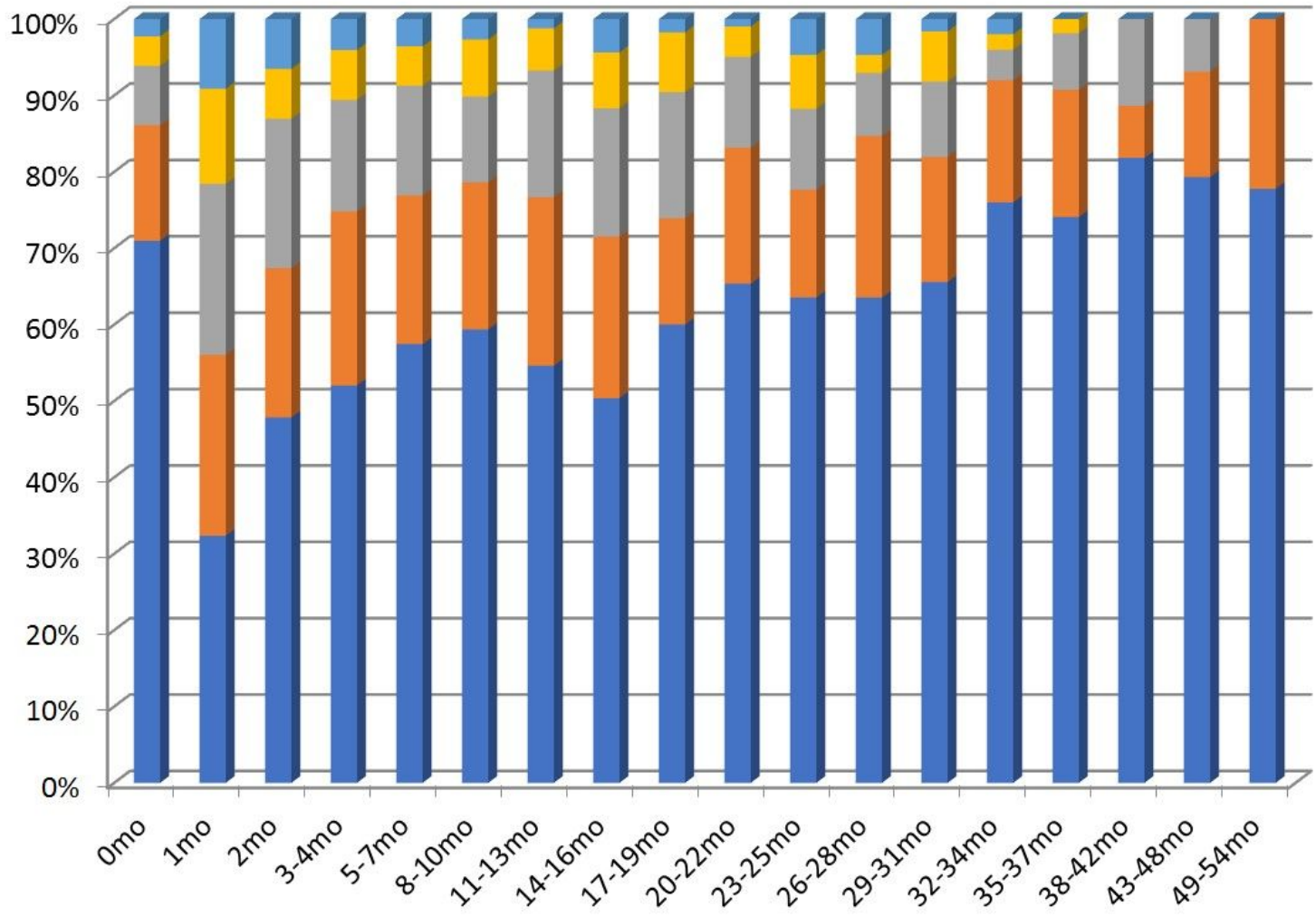

Figure 4

The distribution of answer to subscale GP5 (I am bothered by side effects of treatment) question (not at all: dark blue, a little bit: orange, somewhat: gray, quite a bit: yellow, and very much: sky blue).