



## Original Article

# A study to determine the possible links between subjective (fatigue questionnaires) and objective (bio-mathematical fatigue prevention model) fatigue detection methods

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## ABSTRACT

**Introduction:** Application of objective fatigue detection tools in aviation bases is limited. This study was envisaged to conduct a systematic comparative analysis between a well-established objective method and short fatigue questionnaires which are used in fatigue research to employ them as a fatigue screening tool for aviation personnel.

**Material and Methods:** Thirty-eight aviation personnel volunteered for this cross-sectional observational study. Work-rest/sleep data collected using actigraphy over 1 week were fed to a PC running Fatigue Avoidance Scheduling Tool. Objective fatigue parameters in the form of Fatigue Risk Time (FRT) and Fatigue Free Occupational Time (FFOT) were retrieved. Fatigue questionnaires Groningen Sleep Quality Scale (GSQS) for assessing sleep quality and Stanford Sleepiness Scale (SSS) to detect day-time sleepiness were used as subjective fatigue parameters. Comparative analysis was carried out using appropriate statistical tests.

**Results:** A consistent Total Sleep Time (TST) ranging from 353 to 378 min in the week of the study with no statistically significant differences between the nights were recorded. The increasing trend of FRT and decreasing trend of FFOT over the week were observed. The GSQS, SSS (morning), and SSS (afternoon) also demonstrated a progressive increase in the scores, but only the increase from day 1 to day 2 was statistically significant.

**Conclusion:** Gradual increase in FRT with a reciprocal decrease in FFOT, which was observed, in this study, could be attributed to a progressive increase in sleep debt over the week. A consistent TST of the duration, which is less than the optimal duration of 7–8 h for night sleep, can lead to a gradual increase in sleep debt. The regression equations computed for FFOT was:  $FFOT = 657 + (0.24 \times TST \text{ in min}) - \{(27 \times \text{Morning GSQS}) + (73 \times \text{Day factor})\}$ . This regression equation could be used to extrapolate the fatigue free occupation time for aviation personnel. The study has confirmed the effectiveness of both GSQS and SSS as the fatigue prevention tool and their application in the field setup, especially in the absence of any objective fatigue detection tool.

**Keywords:** Fatigue questionnaires, Objective fatigue detecting tool, Fatigue risk, Fatigue free occupation time

## INTRODUCTION

Detecting fatigue among aviation personnel possesses a great challenge due to the limited practical applicability of fatigue detection tools<sup>[1-3]</sup> in the field set-up such as aviation bases and the lack of objectivity in the method of “self-declaration” by the crew. The short fatigue

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questionnaires, which could be employed to overcome this challenge, are supported by few scientific studies toward assessing their effectiveness as a fatigue detection tool.<sup>[4,5]</sup> This study was envisaged to conduct a systematic comparative analysis between a well-established objective method and short fatigue questionnaires which are used in fatigue research.

Based on Hursh's Bio-mathematical model of Sleep, Activity, Fatigue, Task and Effectiveness, a computerized fatigue prevention tool is available in the open source as Fatigue Avoidance Scheduling Tool (FAST) for use in the aviation organization.<sup>[6,7]</sup> This system was integrated with actigraphy and was used in the past with a recent publication on its validation as an effective fatigue detection tool.<sup>[8,9]</sup> This study emphasized that the system with its performance prediction capability can be employed for detecting crew fatigue through parameters such as Fatigue Risk Time (FRT), Fatigue Free Time (FFT), Fatigue Free Occupation Time (FFOT), and sleep reserve. The time elapsing after getting up from bed in the morning was considered the optimal performance time when the "sleep reserve" was maintained between 90 and 100%. The crew is less likely to suffer from fatigue-induced deterioration of performance. The such period during the duty hour is considered as FFOT provided that the continuous wakefulness is not beyond 18 h (1080 min).

Similarly, the wrist-worn type actigraphy device is capable of assessing sleep through various sleep variables such as Total Sleep Time (TST) and Sleep Efficiency (SE). When integrated, actigraphy makes the fatigue prediction tool FAST robust with more objectivity due to the advantage of limiting subjective bias.

The Groningen Sleep Quality Scale (GSQS), a short questionnaire, is used for assessing the quality of sleep.<sup>[10,11]</sup> This 15-point true/false scale is a paper pencil test, which can be used for a quick assessment in the occupational setting. Stanford Sleepiness Scale (SSS), which is used to detect the level of "alertness," also has the advantages of being short, easy to employ, and interpreted effectively.<sup>[12]</sup>

## MATERIAL AND METHODS

Randomly selected 38 serving aviation personnel in the age of 20–50 years from a military air base were selected using a convenient sampling method. The calculated sample size using G-power software-version 3.1.9.4 by considering acceptable parameters ("Correlation: point biserial model," "Effect size" = 0.5, "alpha error probability to 0.05, and power at 0.95") was 27. The exclusion criteria were personnel with a history of head injury, neurological disorder, or any medications that affect sleep. Written consent was obtained from all eligible participants after explaining the nature

of the study. This cross-sectional observational study was conducted as per the guidelines laid down by ICMR.

### Fatigue questionnaires

The sleep quality of the crew was assessed using the GSQS. The GSQS assessed sleep quality on a 14-item scale. Scores range from 0 to 14, with scores between 0 and 2 indicating normal, refreshing sleep, and scores  $\geq 6$  indicating disturbed sleep. For the present study, a cutoff score of 3, indicating sleep disturbances, was used.<sup>[13]</sup> All participants filled up this questionnaire everyday morning after the pre-flight checks. This scale was meant for assessing the quality of sleep the previous night. Day-time sleepiness, which was the indicator of poor sleep and thereby fatigue, was also assessed for all participants. The SSS was used to assess their perception of their state of sleepiness/alertness. The SSS is a 7-point Likert scale with 7 being the most sleepy and 1 being the most alert. A cutoff score of 4 as an indicator of poor level of alertness was used in our study following the guidelines from the previous studies.<sup>[14]</sup>

The actigraphy data collected using "Actiwatch Spectrum from Philips (Respironics)" were fed to a PC running the FAST software. The fatigue parameters, which were retrieved from this software, were FRT and FFOT. The time duration with the cognitive performance falling below 90% was considered FRT. The "sleep reserve" function of the FAST software was used to compute the FFOT. The sleep variables lie TST and SE were retrieved directly from the actigraphy data.

### Statistical analysis

Patient's demographic data, subjective fatigue parameters (GSQS and SSS scores), and objective fatigue parameters (FRT and FFOT) sleep variables were expressed as mean, mean rank, and SD or percentages. After checking the data for normality by Shapiro–Wilk test and homogeneity by Levene's test, a statistical comparison between the days of the week was made using Kruskal–Wallis (followed by Mann–Whitney *post hoc*) tests for the data violating these assumptions. Correlation analysis was carried out with Pearson's correlation test. Regression analysis was carried out using multiple regression following the "backward-stepwise" method. A statistical package of SPSS version 21.0 for Windows was employed in this study.

## RESULTS

### Demographics

A total of 38 aviation personnel including aircrew from fighter and transport streams participated in the study. The demographic details along with the health habit factors are displayed in Table 1.

**Fatigue parameters**

**FRT and FFOT**

The mean, SD, and mean ranks for FRT and FFOT are displayed in Table 2. The increasing trend of mean FRT and decreasing trend of mean FFOT over the week are depicted in Figure 1.

**Sleep parameters**

The mean, SD, and mean ranks for TST and SE are displayed in Table 3 and Figure 2.

**Fatigue questionnaires**

**GSQS and SSS**

The mean ranks for GSQS, SSS (M), and SSS (Af) along with mean and SD are displayed in Table 4.

**Subjective versus objective fatigue parameters**

**Comparison of mean rank**

The mean ranks of the objective parameters (FRT and FFOT) and subjective parameters (scores of GSQS and SSS) of fatigue were compared sleep variables (TST and SE) using Kruskal–Wallis test. The results are shown in Table 5 and the trends are depicted in Figure 3.

**Table 1:** Demographic details of participants (n=38).

Demographic details	Category	Number	%
Age	20–30 years	26	68.42
	30–40 years	12	31.57
	>40 years	00	
Sex	Male	38	100
	Female	0	0.00
Marital status	Single	21	55.26
	Married	17	44.73
Smoking	Yes	4	10.52
	No	34	89.47
Alcohol	Yes	22	57.89
	No	16	42.10

Both subjective and objective fatigue parameters had demonstrated statistically significant different values on different days of the week. At 4 degree of freedom, F values with respective p values recorded were GSQS ( $F = 22.31, P = 0.000$ ), morning SSS ( $F = 15.39, P = 0.004$ ), afternoon SSS ( $F = 34.91, P = 0.000$ ), FRT ( $F = 66.54, P = 0.000$ ), and FFOT ( $F = 122.59, P = 0.000$ ). However, sleep variables did not show statistically significant changes for TST and SE recorded on various days of the studied week. Mann–Whitney U-tests were conducted to determine the statistically significant pairs to ascertain the increasing or decreasing trends of these parameters. GSQS, SSS (M), and SSS (Af) had demonstrated statistically significant pairs, namely, day 2–day 3, day 3–day 4, and day 4–day 5 with  $p < 0.01$ . However, the objective fatigue parameter FRT demonstrated an increasing trend with a significant rise from day 2 to day 3 and from day 4 to day 5. Conversely, FFOT had shown a decreasing trend with pairs D1–day 2, day 2 to day 3, and day 3 to day 4 showing statistically significant differences.

**Correlation analysis**

A correlation analysis was carried out between subjective fatigue parameters (GSQS and SSS) and objective fatigue parameters (FRT and FFOT) including sleep variables (TST and SE) using Pearson correlation test. The results are shown in Table 6.

**GSQS with sleep variables**

The subjective experience of the sleep quality assessed by GSQS was negatively correlated with TST ( $r = -0.54, P = 0.000$ ) and SE ( $r = -0.31, P = 0.000$ ). The correlations were statistically significant ( $P = 0.000$ ) with a large effect size for TST ( $r = -0.54$ ) and a medium effect size for SE ( $r = -0.31$ ). This analysis indicated that lesser sleep time and lower SE are associated with higher GSQS.

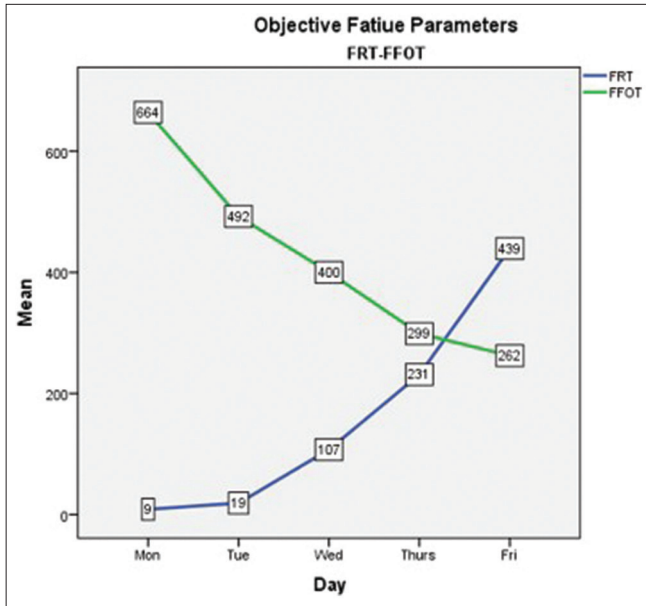
**GSQS with fatigue parameters**

GSQS was positively correlated with FRT ( $r = 0.47, P = 0.000$ ) and negatively correlated with FFOT ( $r = -0.44, P = 0.000$ ). The correlations were statistically significant ( $P = 0.000$ ) with a medium effect size for both FRT ( $r = 0.47$ )

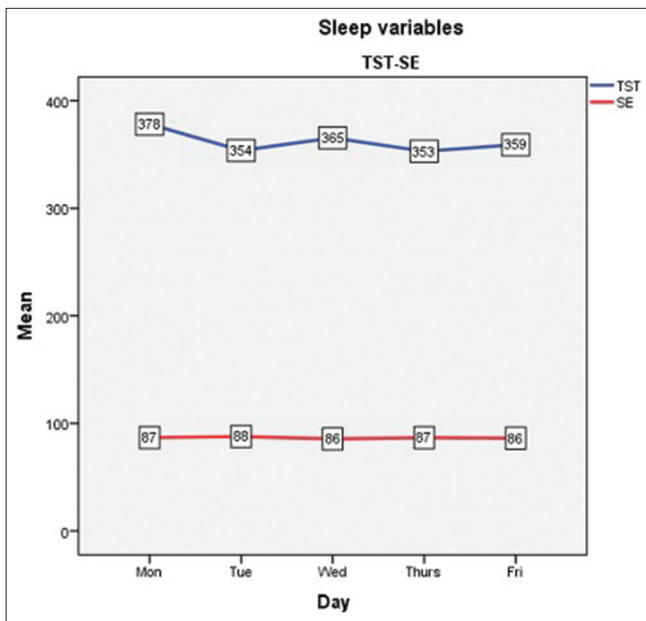
**Table 2:** Mean and mean rank of FRT and FFOT on various days of the week.

	FRT			FFOT		
	Mean (Minutes)	SD	Mean rank	Mean (Minutes)	SD	Mean rank
Day 1 (Monday)	9	18	58.97	664	31	169.38
Day 2 (Tuesday)	19	41	64.95	492	82	117.01
Day 3 (Wednesday)	107	96	97.12	400	129	86.25
Day 4 (Thursday)	231	97	113.97	299	123	56.82
Day 5 (Friday)	439	272	142.49	262	140	48.04

FFOT: Fatigue free occupational time, FRT: Fatigue risk time



**Figure 1:** Fatigue Risk Time (FRT) and Fatigue Free Occupational Time (FFOT) on various days of the week showing increasing (FRT) and decreasing (FFOT) trends.



**Figure 2:** Total sleep time and sleep efficiency on various nights of the week.

and FFOT ( $r = -0.44$ ). The result indicated that the higher GSQS is associated with higher FRT and lower GSQS is associated with higher fatigue free duty time.

#### SSS with sleep variables

The subjective experience of daytime sleepiness assessed by SSS before the start of the duty ( $SSS_M$ ) was negatively

correlated with both TST ( $r = -0.14, P = 0.051$ ) and SE ( $r = -0.30, P = 0.000$ ). Only the correlation with SE was statistically significant ( $P = 0.000$ ) with a medium effect size ( $r = -0.30$ ). However, the correlation of  $SSS_M$  with TST was not statistically significant ( $P = 0.051$ ). Similarly, the subjective experience of daytime sleepiness assessed at the end of the duty during the afternoon ( $SSS_{Af}$ ) was poorly correlated with both TST ( $r = 0.02, P = 0.75$ ) and SE ( $r = 0.02, P = 0.79$ ).

#### SSS with fatigue parameters

$SSS_M$  was positively correlated with FRT ( $r = 0.26, P = 0.000$ ) and negatively correlated with FFOT ( $r = -0.17, P = 0.01$ ). Although the correlations were statistically significant ( $P = 0.000$  and  $0.03$ ), the effect size was small (0.26 for FRT and  $-0.17$  for FFOT). Similarly,  $SSS_{Af}$  was positively correlated with FRT ( $r = -0.18, P = 0.000$ ) and negatively correlated with FFOT ( $r = -0.38, P = 0.000$ ).

#### Regression analysis

To establish the link between the subjective and objective fatigue parameters, a “Simple Multiple Regression” analysis was carried out by considering the fatigue parameter FFOT as a dependent variable. The subjective fatigue parameters such as GSQS, SSS (M), and SSS (Af) and the sleep variables such as TST and SE along with a day of the week were considered as independent variables. The result for the best prediction is shown in Table 7.

A regression model with satisfactory model validity was considered for predicting the objective fatigue parameter FFOT. The significant predictors for FFOT (morning) were TST ( $t = 2.66, P = 0.008$ ), morning GSQS ( $t = -2.45, P = 0.015$ ), and the day of the week ( $t = -16.22, P = 0.000$ ). The strength of association between these predictors and FFOT was indicated by large “Adjusted  $R^2$ ” (0.660) and “F value” of 123.01 with  $P < 0.001$ .<sup>[15]</sup> Regression equation for calculating the FFOT in the morning before start of the duty was also computed.

#### DISCUSSION

This cross-sectional observational study was conducted to assess fatigue among aviation personnel during their duty time. FRT and FFOT were retrieved from a bio-mathematical model “FAST” and used as the objective fatigue parameters. The mean FRT among the participants had shown an increase with minimum value of 9 min on day 1 to maximum value of 439 min on day 5 with the statistically significant rise from day 2 to day 3 and day 3 to day 4. On the contrary, the mean FFOT displayed a statistically significant decrease from a maximum value of 664 min on day 1 to a minimum value of 262 min on day 5. Gradual increase in FRT with a reciprocal decrease in FFOT, which was observed in this study, could be attributed to

**Table 3:** Mean of TST and SE on various nights of the week retrieved from actigraphy data.

	TST			SE		
	Mean (Min)	SD	Mean rank	Mean (%)	SD	Mean rank
Night 1 (Sunday)	378	105	103.41	86.7	5.5	89.24
Night 2 (Monday)	354	73	94.97	87.8	8.3	105.21
Night 3 (Tuesday)	365	128	91.43	85.6	11.7	97.84
Night 4 (Wednesday)	353	95	93.43	86.7	8.2	95.20
Night 5 (Thursday)	359	100	94.25	86.2	7.5	90.01

TST: Total sleep time, SE: Sleep efficiency

**Table 4:** Mean, median, and mean ranks of GSQS, SSS (M), and SSS (Af) on various days of the week.

	GSQS			SSS (M)			SSS (Af)		
	Mean	Median	Mean rank	Mean	Median	Mean rank	Mean	Median	Mean rank
Day 1 (Monday)	1.18	1	63.51	1.11	1	73.87	3.24	3	57.01
Day 2 (Tuesday)	1.29	1	82.17	1.47	1	106.76	3.89	4	89.53
Day 3 (Wednesday)	1.45	1	90.70	1.39	1	88.21	4.05	4	99.63
Day 4 (Thursday)	1.71	2	108.71	1.58	1	103.87	4.18	4	108.22
Day 5 (Friday)	1.97	2	111.41	1.71	1	104.79	4.47	4	123.11

GSQS: Groningen Sleep Quality Scale, SSS: Stanford Sleepiness Scale

**Table 5:** Results of Kruskal–Wallis tests (with Mann–Whitney U-tests for pairwise comparisons) for subjective and objective fatigue parameters.

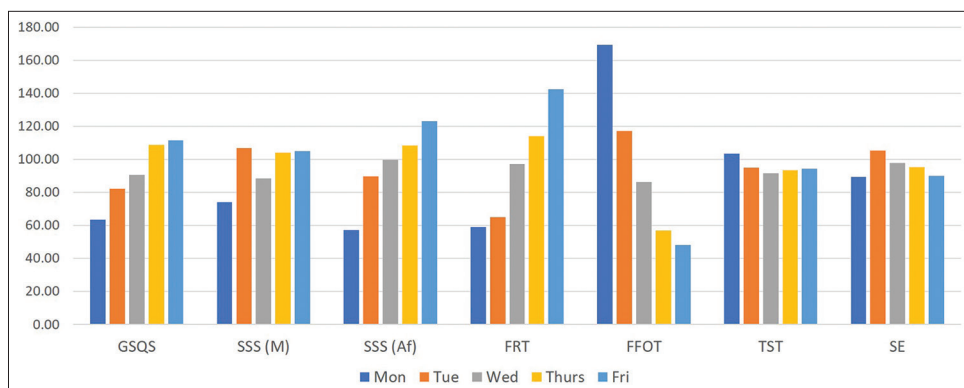
	GSQS	SSS (M)	SSS (Af)	FRT	FFOT	TST	SE
Chi-square	22.318	15.396	34.91	66.548	122.599	1.07	2.126
df	4	4	4	4	4	4	4
Asymp. Sig.	0.000	0.004	0.000	0.000	0.000	0.899	0.713
Pairwise comparisons with Mann–Whitney U-tests for $P < 0.015$							
Day 1 versus day 2	0.012	0.000	0.003	0.475	0.000	--	--
Day 2 versus day 3	0.510	0.071	0.340	0.002	0.001	--	--
Day 3 versus day 4	0.158	0.138	0.405	0.092	0.002	--	--
Day 4 versus day 5	0.241	0.862	0.141	0.010	0.175	--	--
Day 1 versus day 3	0.169	0.091	0.000	0.000	0.000	--	--
Day 1 versus day 4	0.004	0.001	0.000	0.000	0.000	--	--
Day 1 versus day 5	0.000	0.000	0.000	0.000	0.000	--	--

FFOT: Fatigue free occupational time, GSQS: Groningen Sleep Quality Scale, TST: Total sleep time, SE: Sleep efficiency, FRT: Fatigue risk time, SSS: Stanford Sleepiness Scale

a progressive increase in sleep debt over the week. A consistent TST of the duration, which is less than the optimal duration of 7–8 h for night sleep,<sup>[16]</sup> can lead to a gradual increase in sleep debt. This was confirmed by analyses of the actigraphy based sleep data of the participants. A consistent TST ranging from 353 to 378 min in the week of the study with no statistically significant differences between the nights was recorded.

GSQS was used in the morning during the pre-flight checks to assess the sleep of the previous night. Considering 3 as the cutoff value for GSQS score for marking as poor sleep,<sup>[13]</sup> the number of participants who had poor sleep in their previous nights was on 2 on day 1 (5.2%), 2 on day 2 (5.2%), 6 on day 3 (15.7%), 7 on day 4 (18.4%), and 9 on day 5 (23.6%).

The majority of our participants had low GSQS in the in the studied week. The subjective experience about a good sleep is attributed to the amount of slow wave sleep in the previous night. In a night sleep of 6–7 h, this part of the sleep gets fulfilled and only when the sleep is reduced to <5 h, the experience of good sleep gets affected though there is an individual variation.<sup>[17,18]</sup> The sleep with TST averaging about 6 h could have resulted low GSQS in our participants. Similarly, the day-time sleepiness as an indicator of fatigue due to sleep deprivation was also determined using SSS both during morning time, that is, before start of the duty and at the end of the duty at 1400 h in the afternoon. Considering 4 as the cutoff value for the SSS score,<sup>[14]</sup> the day-time



**Figure 3:** The mean ranks for GSQS, Stanford Sleepiness Scale (m), Stanford Sleepiness Scale (Af), fatigue risk time, fatigue free occupational time, total sleep time, and sleep efficiency on various days of the week.

**Table 6:** Correlation coefficient (r) between various subjective fatigue parameters (GSQS and SSS) with objective fatigue parameters (FRT and FFOT) and objective sleep parameters (TST and SE) using Pearson correlation test.

	GSQS	SSS (M)	SSS (Af)	FRT	FFOT	TST	SE
GSQS		0.001	0.01	0.000	0.000	0.000	0.000
SSS (M)	0.23		0.42	0.000	0.01	0.051	0.000
SSS (Af)	0.18	0.06		0.01	0.000	0.75	0.79
FRT	0.47	0.26	0.18		0.000	0.000	0.04
FFOT	-0.44	-0.17	-0.38	-0.60		0.000	0.83
TST	-0.54	-0.14	0.02	-0.31	0.25		0.000
SE	-0.31	-0.30	0.02	-0.15	0.02	0.29	

Above the diagonal – Statistics, below the diagonal – P value Effect size for the correlation as per the Cohen’s standard: Small (0.10–0.29), medium (0.30–0.49), and large (0.50 and above) FFOT: Fatigue free occupational time, GSQS: Groningen Sleep Quality Scale, TST: Total sleep time, SE: Sleep efficiency, FRT: Fatigue risk time, SSS: Stanford Sleepiness Scale

**Table 7:** Result of multiple regression for predicting FFOT considering various subjective fatigue parameters and sleep parameters as predictors using the backward stepwise method.

Independent variables	Unstandardized coefficients		Standardized coefficients	t	Sig
	B	Std. error	Beta		
(Constant)	656.710	44.060		14.905	0.000
Week days	-73.456	5.762	-0.734	-16.220	0.000
GSQS	-26.518	10.806	-0.131	-2.454	0.015
TST	0.242	0.091	0.136	2.666	0.008
Model validity	F	p	R <sup>2</sup>	Adjusted R <sup>2</sup>	Durbin-Watson
	123.01	0.000	0.665	0.660	1.777

Regression equation for calculating FFOT in the morning  $GSQS$  and  $TST$ ,  $FFOT = 657 + (0.24 \times TST \text{ in min}) - \{(27 \times \text{Morning } GSQS) + (73 \times \text{Day factor})\}$ , [Day Factor 1 for Monday, 2 for Tuesday, 3 for Wednesday, 4 for Thursday, and 5 for Friday], FFOT: Fatigue free occupational time, GSQS: Groningen Sleep Quality Scale, TST: Total sleep time

sleepiness recorded in the morning as SSS (M) on various days was day 1 (0), day 2 (0), day 3 (2), day 4 (2), and day 5 (4). This indicates that the number of crew experiencing daytime sleepiness in the morning was few. In the survey by Taneja,<sup>[19]</sup> documented the same about reporting of fatigue by the crew during morning pre-flight checks. Day-time sleepiness is a function of Stage 1 and Stage 2 of NREM

sleep. Any amount of sleep if is not reduced to <5 h the part of the sleep architecture remains fulfilled and consistent. The proportionately lesser participants had a night sleep of <5 h duration in the entire week of the study period, which could be the explanation for a consistently low SSS (M) on all days of the week. However, when the same was recorded in the afternoon after the duty time as SSS (Af), the number of

participants showing deteriorated alertness was 16 (42.1%) on day 1, 25 (65.7%) on day 2, 30 (78.9%) on day 3, 32 (84.2%) on day 4, and 34 (89.4%) on day 5. Furthermore, SSS (Af) was consistently higher than the respective values of SSS (M) on all days of the week. This was an indication of subjective fatigue experienced by the participating crew toward the end of their duty period. The length of the duty time and the amount of sleep before the duty period are the known modifiable risk factors toward occurrence of occupational fatigue.<sup>[20]</sup> The appreciation of this fact and awareness of the crew on the subject were well documented.<sup>[21,22]</sup> The results of our study are supporting the occurrence of occupational fatigue and the potential causative factors.

### Subjective versus objective parameters

A negative correlation was observed between GSQS and TST as well as between GSQS and SE, which means that the subjective experience of the participants about their night sleep can be attributed to the quantity and quality of sleep of the previous night. This finding of our study is supported by the physiological phenomenon related to night sleep. REM sleep, which normally occurs toward the end of the night, gets affected due to sleep of lesser duration. A similar negative correlation was observed between the fatigue parameter FFOT and SSS (Af). Possible sleep debt due to a consistent TST averaging about 6 h against the requirement of 7–8 h for optimum night sleep in association low level of alertness due to circadian rhythm could be the explanation for subjective fatigue. Fatigue, especially with a symptom of daytime sleepiness during the duty period, affects the fatigue free occupation time. This is an important finding of the study since it supports the need for the employability of this fatigue detection questionnaire as a tool for detecting fatigue among aircrew during extended when flying operations.<sup>[23]</sup>

### Fatigue predication model

Considering the fatigue free period as an important need for optimization of crew performance in a critical occupation like flying, the prediction for FFOT from the subjective fatigue parameters and objective sleep variables was modeled. The regression model used in our study confirmed GSQS, TST, and the day of the week as the statistically significant “predictors” for FFOT. The regression equations computed for FFOT were:  $FFOT = 657 + (0.24 \times TST \text{ in min}) - \{(27 \times \text{Morning GSQS}) + (73 \times \text{Day factor})\}$ . This regression equation could be used to extrapolate the fatigue parameter in the absence of a sophisticated objective fatigue monitoring tool.

### CONCLUSION

Fatigue is a big “NO-GO” in aviation. The deterioration of cognitive performance is known when the crew is under

fatigue. There are reports to establish fatigue as the primary contributor to various aviation accidents. Therefore, fatigue needs to be detected and mitigated before the aviation personnel commences flying-related duties. With studies confirming the roles of objective and subjective fatigue detecting tools, the number is limited when comparing their effectiveness. This study was undertaken to assess fatigue using both subjective tools in the form of “Fatigue questionnaires” and an objective tool in the form an “Actigraphy integrated fatigue avoidance scheduling tool (FAST)” and compare the results of both for the determination of any possible link. The study has confirmed the effectiveness of both GSQS and SSS as the fatigue prevention tool and their application in the field setup, especially in the absence of any objective fatigue detection tool.

### Declaration of patient consent

Patient’s consent not required as there are no patients in this study.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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