The health-related quality of life in patients with dry eye syndrome: a cross-sectional study in Thailand

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Abstract

Background Dry eye syndrome (DES) is common but lack of data in guality of life (QoL) of DES patients in Thailand. The primary outcome of this study was to determine QoL and health utility in patients of DES by EuroQol 5-domain (EQ-5D) of the 5-level version (5 L) instrument. The secondary outcome was comparison of the utility in the patients of DES classified by severity and causes including the autoimmune and non-autoimmune diseases.

Method The study was a cross-sectional study at a hospital in the northern part of Thailand. The inclusions DES patients were followed by Tear Film and Ocular surface Society the Dry Eve WorkShop II definition. The EO-5D-5 L (Thai version) descriptive system and the EQ visual analogue scale (VAS) was instrument for QoL evaluation.

Result Total patients of DES were fifty-six. The most patients were female. The mean age was 57.7(±13.9) years. The mean of EQ-5D-utility and EQ-VAS were 0.76 (±0.18) and 72.56 (±15.19), respectively. The mean of EQ-5D-utility in these patients who were classified by severity including mild, moderate and severe were 0.84 (±0.16), 0.78 (±0.14) and 0.71 (\pm 0.22), respectively. There is no statistic significant in the EQ-5D-utility and EQ-VAS among severity and the causes of these patients.

Conclusions This study demonstrated the importance of assessing QoL in DES. The EQ-5D-utility was accorded with the severity of DES. However, no statistic significant was showed in the mean of EQ-5D-utility and EQ-VAS between the severity and between the causes including the autoimmune and non-autoimmune diseases of these patients.

Keywords Quality of life, Dry eye syndrome, Utility, Autoimmune, EQ-5D-5L

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Background

Dry eyes syndrome (DES) was a common eye condition in the aging population [1], especially in females [2]. DES could affect a patient's physical health, including pain, asthenopia, photophobia, blurred vision and poor sleep quality. In addition, it could also affect a patient's working abilities, psychological health, and quality of life [3, 4].

The prevalence of DES varied from 5 to 50% of the general population, depending on the definition of DES and patients' characteristics [1]. The common causes of DES were autoimmune or non-autoimmune disorders, androgenic hormonal change, environmental factors (such as particulate matter < 2.5 and 10 μ m) and lifestyle factors such as long working time [5]. Some medications that could also cause DES, such as antihistamines, antidepressants and oral steroids, were causes of DES from systemic medications usage [6].

Among causes of non-autoimmune DES, aging was the major cause of DES as anatomical and inflammationinduced age-related changes [7]. The eye components were eyelid changes, lacrimal glands, conjunctiva, meibomian gland and ocular surface health were effected by aging [7]. Primary and secondary Sjogren's syndrome and Graves' ophthalmopathy were commonly reported as the causes of DES among autoimmune diseases [8]. However, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), which provide a combination of structural and functional damage to the ocular surface system, result in aqueous tear deficiency, decreased wettability and increased evaporation, cause serious ocular surface abnormality and DES [8–10]. DES was the most common late complication in SJS and TEN [11]. DES affected QoL and the utility of patients [12].

An important outcome of interest for cost-utility analysis was the quality-adjusted life year (QALY) [13]. The utility was an assessment method for quantifying and understanding a health state in each disease [14] which is used to estimate QALY along with the patient's life year. Thus, utility is a measure that is essential to determine QALY for cost-utility analysis [13]. Finally, the data on the utility of one country across another was the potential inaccuracies in the cost-utility analysis [15].

In DES, the utility depended on the severity of DES and the tool used for its evaluation. The highest and lowest utility weights were reported in mild and severe DES patients. However, the utility of DES was reported in a few studies using the time trade-off (TTO), standard gamble (SG) methods, or the Health Utilities Index Mark 3 [14, 16, 17]. The EuroQol 5-domain (EQ-5D) of the 5-level version (5 L) instrument was a concise and basic measure of self-reported health [12]. The EQ-5D-5 L can be used to elicit the utility scores in general population [18] and also recommended to use for health utility measurement for health technology assessment [19, 20].

Moreover, the EQ-5D-5 L has better psychometric properties than the EQ-5D-3 L in both general Thai population and chronic diseases [21–23].

Nevertheless, the utility of Thai patients with DES has not been evaluated. It is important for further health economic evaluation of health interventions and technologies for patients with DES in Thailand to have utility values. Therefore, this study aimed to measure the utility values in patients with DES in Thailand.

Materials and methods

Overall study design and participant selection

This study was a cross-sectional study at a university hospital in the northern part of Thailand. The eligible patients were assessed and recruited by three ophthalmologists at outpatient ophthalmology clinic at the setting. The inclusion criteria were patients visiting the out-patients ophthalmology clinic from May to August 2023, patients aged 20 years old or more, patients were diagnosed as DES based on The role of the Tear Film and Ocular Surface Society (TFOS) Dry Eye Workshop (DEWS) II criteria [24, 25]. Finally, patients agreed to participate and able to respond to the EQ-5D-5 L questionnaire (Thai version). Patients who were unable to understand the questionnaire or had asymmetrical severity of DES or unable to complete the questionnaire were excluded. The study protocol was approved by an Institute Review Board and Ethics Committee (IRB No. P3-0041/2565).

Sample size estimation

A related study on health utility among patients with DES reported a mean and standard deviation of 0.81 and 0.19, respectively [16]. Using the mean and standard deviation abovementioned with the alpha=0.05 and absolute error=0.05, the estimated number of required patients were 56 patients.

Measurements

The EQ-5D-5 L (Thai version) was used to determine the patient's utility. The permission to use the EQ-5D-5 L (Thai version) instrument [20] was obtained from the EuroQol group (https://euroqol.org/). The EQ-5D-5 L has five main dimensions including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has five levels of response including 1-no problem, 2-slight problem, 3-moderate problem, 4-severe problem and 5-extreme problem. In addition, the EQ- Visual Analog Scale (VAS) was also used to be a self-rated health utility with a continuous scale of 0 to 100. 0 represents "The worst health participants can imagine". The EQ-5D-5 L (Thai version) instrument is valued to utility score using the Thai EQ-5D-5 L

algorithms. We used the equation from the hybrid model for utility calculation as recommended by the authors of the study [20].

Data collection

Patients were assessed for eligibility by ophthalmologists. Patients who were eligible for the study and agreed to participate in this study were interviewed by two research assistants, who are the study nurses at the clinic. The data collectors were trained to interview EQ-5D-5 L. The data were inspected to ensure the validity of data by ophthalmologists.

Statistical analysis

Baseline characteristics and outcomes were descriptively analyzed using descriptive statistics. Frequencies and percentages were used for categorical data. Mean and standard deviation were used for continuous data if they were normally distributed, while median and interquartile range (IQR) were used for continuous data if they were not normally distributed. Histogram along with Kolmogorov-Smirnov test were used to examine the distribution of data. The *p*-value of less than 0.05 of Kolmogorov-Smirnov test indicated the non-normally distributed data. One-way analysis of variance (ANOVA)

Table 1	The baseline characteristics of DES	patients
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or Kruskal-Wallis were used to compare continuous data among different severities of DES, while chi-square test was used to compare categorical data among different severities of DES. The statistical significance was considered with *p*-value less than 0.05.

All analyses were performed using STATA version 17.0.

Results

Patient characteristics

A total of 56 patients with DES were enrolled. Most patients (94.6%) were female. The mean age was 59.7 (\pm 13.9) years old. The median time from diagnosis of DES was 4.7 years (IQR=2.2 to 6.8 years). The common cause of DES associated was autoimmune disease. Primary Sjogren syndrome and idiopathic causes were the most common causes in autoimmune diseases and non- autoimmune diseases, respectively. In autoimmune disease, most patients (41.18%) were Stevens-Johnson syndrome (SJS) or toxic epidermal necrosis (TEN). The most common causes of non-autoimmune diseases were idiopathic. Patient characteristics by the severity of DES were reported in Table 1.

Variables	Total N=56 (%)	Mild n=13 (%)	Moderate n = 19 (%)	Severe n=24 (%)	<i>p</i> -value
Female	53(94.64)	12(92.31)	18(94.74)	23(95.83)	0.902
Age, years, mean (± SD)	59.7(13.9)	60.9(16.7)	61.9(13.7)	57.4(12.7)	0.549
Duration of DES^{**} , years, median (IQR $^{\&}$)	4.7(2.2,6.8)	2.6(1.9,4.8)	4.9(3.5,6.0)	5.3 (3.0,9.1)	0.159
Causes of DES					
Autoimmune disease	(N=32) (%)	(<i>n</i> =4) (%)	(<i>n</i> =11) (%)	(<i>n</i> =17) (%)	
- Sjogren syndrome	8/32(25)	1/4(25)	3/11(27.27)	4/17(23.53)	
- SJS ⁺ and TEN [#]	7/32(21.88)	-	-	7/17(41.18)	
- Systemic Lupus Erythematosus	5/32(15.63)	1/4(25)	3/11(27.27)	1/17(5.88)	
- Rheumatoid arthritis	7/32(21.88)	-	2/11(18.19)	5/17(29.41)	
- HLA ^{\$} -B 27 associated diseases	2/32(6.25)	1/4(25)	1/11(9.09)	-	
- Anterior uveitis	1/32(3.12)	1/4(25)	-	-	
- Mixed Connective Tissue Disease	1/32(3.12)	-	1/11(9.09)	-	
- Dermatomyositis	1/32(3.12)	-	1/11(9.09)	-	
Non-autoimmune disease	(N=24) (%)	(<i>n</i> =9) (%)	(<i>n</i> =8) (%)	(<i>n</i> =7) (%)	
- Pinguecula or pterygium	2/24(8.33)	1/9(11.11)	1/8(12.50)	-	
- Toxic medicamentosa	2/24(8.33)	-	1/8(12.50)	1/7(14.29)	
- Prior corneal abrasion	2/24(8.33)	2/9(22.22)	-	-	
- Post corneal incision	2/24(8.33)	2/9(22.22)	-	-	
- Limbal stem cell deficiency	1/24(4.17)	-	-	1/7(14.29)	
- Meibomian gland dysfunction	1/24(4.17)	-	1/8(12.50)	-	
- Prior herpes simplex keratitis	1/24(4.17)	-	-	1/7(14.29)	
- Exposure keratopathy	1/24(4.17)	-	-	1/7 (14.29)	
- Trachoma	1/24(4.17)	-	-	1/7 (14.29)	
- Idiopathic	11/24 (45.83)	4/9 (44.45)	5/8 (62.50)	2/7 (28.55)	

^{**}Dry eye syndrome, [&] Inter-quartile range, ⁺ Stevens-Johnson syndrome, [#] Toxic epidermal necrolysis, ^{\$} Human Leukocyte Antigen

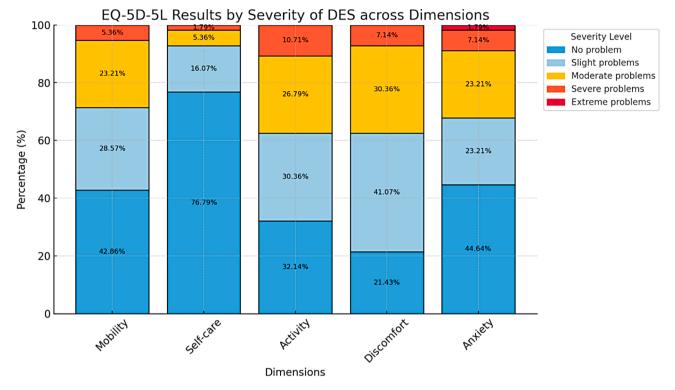


Fig. 1 The results of EQ-5D-5 L were classified by severity of DES and each dimension

 Table 2
 EQ-5D-5 L, EQ-5D-utility and EQ-VAS were classified by severity of DES

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Variables	Total N=56	Mild <i>n</i> = 13	Moderate n=19	Severe n=24	<i>p-</i> val-
					ue
Utility, mean	0.76	0.84	0.78	0.71	0.118
(± SD)	(±0.18)	(±0.16)	(± 0.14)	(±0.22)	
Visual analog	72.86	67.31	74.47	74.58	0.329
scale, mean	(±15.19)	(±15.76)	(±15.71)	(±14.36)	
(± SD)					

Health utilities

According to EQ-5D-5 L, the patients reported no problem on mobility (42.3%), self-care (78.8%) activity (32.1%) and anxiety/depression (46.2%). However, most patients had slightly discomfort problem (41.1%). Each dimension of EQ-5D-5 L, classified by the severity of DES, was reported in Fig. 1. The average utility values and EQ-VAS of all patients were 0.76 (\pm 0.18) and 72.86 (\pm 15.19), respectively. In addition, the average utility values by the severity of DES were 0.84 (\pm 0.16), 0.78 (\pm 0.14), 0.71 (\pm 0.22) for mild, moderate and severe DES, respectively. The average EQ-VAS was 72.86 (\pm 15.19) in all patients of DES. All utility values and EQ-VAS by the severity of DES were reported in Table 2.

No statistically significant differences in the average utility and EQ-VAS between the autoimmune versus non-autoimmune diseases, and among mild, moderate, and severe DES were observed in Table 3.

Discussions

To our knowledge, our study is the most updated study to utilize the EQ-5D-5 L to estimate the utility of DES. In this study, the average utility values and the EQ-VAS

Table 3 EQ-5D-5 L, EQ-5D-utility and EQ-VAS were classified by autoimmune and non-autoimmune diseases with severity of [utoimmune and non-autoimmune diseases with severity of DES
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Variables	Total	p*-value	Mild	Moderate	Severe	<i>p</i> -value
	N=56		n=13	n=19	n=24	
Utility, mean (±SD)						
Autoimmune (n=32)	0.75 (±0.21)	0.639	0.88 (±0.17)	0.80 (±0.16)	0.70 (±0.23)	0.206
Non-autoimmune (n = 24)	0.78 (±0.15)		0.81 (±0.16)	0.77 (±0.12)	0.74 (±0.17)	0.616
Visual analog scale, mean (±	SD)					
Autoimmune (n=32)	75.78 (±14.21)		76.25 (±7.5)	74.09 (±18.14)	76.76 (±13.10)	0.893
Non-autoimmune (n = 24)	68.96 (±15.88)	0.097	63.33 (±17.14)	75 (±12.82)	69.29 (± 16.94)	0.332

*p-value compared utility and visual analog scale between autoimmune and non- autoimmune

in all DES patients were 0.76 (\pm 0.18) and 72.86 (\pm 15.19), respectively. The utility decreased accordingly with the less severity of DES. the VAS-EQ accorded with the utility. No statistical significance was demonstrated in the mean utility and EQ-VAS among the severity and between autoimmune and non-autoimmune causes of DES in this study.

DES that characterized a complex functional disorder [26], particularly a disorder of the preocular tear film was a common problem in ophthalmic condition [5]. Finally, it had affected to normal vision [5] and quality of life (QoL) [17]. There was closely relationship between the QoL and the health state or disease on patient lives and the utility [12] especially DES [17].

Utility of dry eyes had been evaluated by few studies using time trade-off [16] or both time trade-off and standard gamble [14] and by the Health Utilities Index Mark 3 [17]. Using EQ-5D-5 L method, the utility values in the present study was closely comparable to a previous studies that evaluated by the time trade-off method [16]. Therefore, we hypothesized that the different tool and diagnostic criteria for including the patients of DES had not affect to the utility of DES. On the other hand, the utility of our study had different from a study of Buchholz et al. [14]. The utility between both studies had different as the different methodology and aim of the study [14].

The concerning of relationship between the cause of DES including autoimmune and non-autoimmune disease and its consequence on health-related quality of life, we expected that autoimmune and non-autoimmune dry eyes might have different impact on quality of life. Therefore, this study classified dry eyes patients into autoimmune and non-autoimmune patients. Nevertheless, there was not any statistical significance between the utility and EQ-VAS between the groups. This result demonstrated that the causes including autoimmune and non-autoimmune disease of DES might not be associated factors of the utility and EQ-VAS.

Our study showed that the severity of DES affects the quality of life regardless of its etiology, but the nature of some diseases, particularly SJS and TEN, demonstrated that their symptoms of DES were severe. Moreover, the utility of present study that had the most cause among severe DES was SJS and TEN was lowest value. The common late ocular complications of SJS and TEN was DES [11]. The morphological change and the decreasing of goblet cell density in lacrimal gland [27–29] that effected to aqueous and liquid tear film [30], the effect of meibomian gland including inflammation, atrophy and dropout [29] that effected to lipid component of the preocular tear film [30] were pathological changing in SJS. These pathological changes were described as the cause of severe DES in SJS and TEN patients.

Although clinical presentations of DES are depending on severity and causes of DES including autoimmune and non-autoimmune diseases, all DES similarly effect and no statistically significant on QoL that reflected by utility in our study. Therefore, optimal treatments of all DES patients should be considered to improve QoL, regardless severity or the causes of DES. The invert value between the utility with EQ-VAS score including total and in subgroup analysis by the cause of DES was demonstrated in this study. We proposed that participants with less severe diseases were more cautious about their health.

Although DES patients might have comorbidities; ocular diseases and comorbidity of systemic diseases, EQ-VAS was performed to evaluate the utility of DES subgroups.

There were major strengths in this study. As a few previous studies used TTO and SG methods for evaluation the utility [14, 16]. In this study, EQ-5D-5 L was selected in due to simple, self-reported health [12] that had decreasing interviewer bias, current adjustment and real life that had not to life expectancy [31] or time dependent [32] for TTO and SG, respectively. However, EQ-5D-5 L does not have the dimension related to vision problems, so it may affect the accuracy of utility measurement from the EQ-5D-5 L questionnaire because EQ-5D-5 L is not tailored for any disease, and may not be appropriate for some patients such as those with dental diseases and visual ailments. Further studies using complimentary tools such as the National Eye Institute Visual Function Questionnaire (NEI VFQ-25) or the Ocular Surface Disease Index (OSDI) should be considered. These tools could provide a more comprehensive view of DES's impact, capturing vision-related aspects that EQ-5D may not detect. A dual approach using both general utility measures (like EQ-5D) and disease-specific instruments to measure utility scores or other general quality of life questionnaires like the SF36 and WHOQOL would enhance understanding of both general health and vision-specific quality of life impacts.

The limitations of this study should be discussed. First, the sample size estimation of this study was based on the descriptive nature of overall patients corresponding to the primary outcome of this study, aiming to determine QoL and health utility in the overall patients with DES. It was not calculated for subgroup analyses regarding severity and etiology of DES. Although no statically significant difference between subgroup analysis including by severity and causes of DES that were autoimmune and non-autoimmune diseases yet was also our hypothesis from our results in these subgroups analysis, the next study focusing in these important points should be conducted in order to in the future. As there were many classification criteria for diagnosis of DES, the study selected only TFOS DEWS II as our inclusion criteria for patients of DES. Therefore, there might be different if other criteria for patient diagnosis was applied. However, this limitation might not affect our findings because there were consistent results between our findings and previous findings with different criteria for diagnosis of DES [14, 16, 17]. As we observed some differences of utility in patients with DES, the differences might or might not be clinical meaningful depending on the magnitude of the differences. However, as we have known, there is no minimally clinical important difference (MCID) of health utility measured by ED-5D among patients with DES. Further studies determining the clinical meaningful of health utility in such patients are warranted.

In conclusion, our study provided a quantitative overall summary score of utility in patients with DES and classified by the severity of DES. Patients with greater severity of DES tended to have lower utility regardless of the etiology. Our findings could be an important information for further health economic evaluation of health interventions and technologies for patients with DES in Thailand.

Abbreviations

DES	Dry eye syndrome
TFOS	Tear Film and Ocular Surface Society
DEWS	Dry Eye Workshop
EQ-5D	EuroQol 5-domain instrument
EQ-5D-5L	EuroQol-5-domain instrument-5-level version
IQR	Inter-quartile range
5L	5-level version
HLA	Human Leukocyte Antigen
QALY	Quality-adjusted life year
QoL	Quality of life
SJS	Stevens-Johnson syndrome
TEN	Toxic epidermal necrolysis
VAS	Visual Analog Scale

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Author contributions

PhT., PT., NU. and PD. designed the study protocol. RK., TP. and JS. had collected data at Naresuan University Hospital. PhT. mainly wrote manuscript. The manuscript with critically intellectual content was revised by PT. and PD. The final version of manuscript was accepted and also approved by all authors. Finally, all authors have approved the submitted version and have approved both to be personally accountable for the author's own contributions. All authors ensure that questions related to the accuracy of any part of the work, even ones in which the author was not personally involved, are investigated, resolved, and the resolution documented in the literature.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval

Ethical approval was achieved by the Naresuan University Institutional Review Board and Ethics Committee (IRB No. P3-0041/2565). The Ethics Committees were in accordance with the Declaration of Helsinki.

Consent to participate

Informed consent was obtained from all including dry eye syndrome patients.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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