

**ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE  
USING SPECIFIC STRABISMUS QUESTIONNAIRE  
ON PRE- AND POST-STRABISMUS SURGERY IN  
CHILDREN WITH INFANTILE ESOTROPIA  
AND THEIR PARENTS**

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## **DISCLAIMER**

I hereby certify that the work in this dissertation is my own except for the quotations and summaries which have been duly acknowledged.

Date : 21st May 2019

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# **PENILAIAN KUALITI KEHIDUPAN BERKAITAN KESIHATAN MENGGUNAKAN SOALAN SOAL SELIDIK KHAS BERKAITAN PRE DAN PASCA PEMBEDAHAN JULING DI KALANGAN KANAK-KANAK PENGIDAP *INFANTILE ESOTROPIA* DAN IBU BAPA MEREKA**

## **ABSTRAK**

**Pengenalan:** Kanak-kanak yang menghidapi *infantile esotropia* dan ibu bapa mereka menghadapi pelbagai masalah fungsi dan psikososial. Tetapi, didapati kekurangan pengetahuan tentang impak *infantile esotropia* dan kesan dari pembedahan juling terhadap kanak-kanak dan ibu bapa mereka.

**Objektif:** Untuk menilai kualiti kehidupan kesihatan sebelum dan selepas pembedahan juling di kalangan kanak-kanak yang menghidapi *infantile esotropia* dan ibu bapa/penjaga dengan menggunakan borang soal selidik IXTQ yang diterjemahkan kepada Bahasa Malaysia.

**Methodologi:** Kajian prospektif dijalankan di Klinik Oftalmologi, Hospital Wanita dan Kanak-kanak Sabah dan Hospital Universiti Sains Malaysia dari Jun 2017 hingga November 2018. Kanak-kanak dan ibu bapa/penjaga mereka diminta untuk menjawab borang soal selidik IXTQ versi Melayu sebanyak dua kali iaitu sebelum dan tiga bulan selepas pembedahan. Jumlah purata skor dan skor untuk tiga sub-skala iaitu dari segi fungsi, psikososial dan pembedahan dikira dan dibandingkan sebelum dan selepas

pembedahan.

**Keputusan:** Seramia 34 kanak-kanak yang menghidapi *infantile esotropia* dalam lingkungan umur 8-17 tahun berserta salah satu orang ibu bapa/penjaga mereka yang menemani telah direkrut. Tiga belas (38.2%) kanak-kanak mempunyai *esotropia* melebihi 50 prisma diopter. Tiga puluh tiga (97.1%) kanak-kanak telah berjaya dibetulkan masalah juling mereka. Pembedahan juling telah meningkatkan jumlah skor purata untuk kanak-kanak dengan signifikan, iaitu 62.87 sebelum pembedahan dan 87.13 selepas pembedahan ( $p < 0.001$ ). Peningkatan yang signifikan didapati dalam jumlah purata skor untuk ibubapa, iaitu 37.07 sebelum pembedahan dan 75.39 selepas pembedahan ( $p < 0.001$ ). Skor tiga sub-skala juga menunjukkan peningkatan yang signifikan selepas pembedahan ( $p < 0.001$ ).

**Kesimpulan:** Skor purata untuk kajian kualiti kehidupan kesihatan di kalangan kanak-kanak yang menghidapi *infantile esotropia* dan ibu bapa mereka telah meningkat dengan signifikan selepas pembedahan juling.

# ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE USING SPECIFIC STRABISMUS QUESTIONNAIRE ON PRE- AND POST-STRABISMUS SURGERY IN CHILDREN WITH INFANTILE ESOTROPIA AND THEIR PARENTS

## ABSTRACT

**Introduction:** Children with infantile esotropia and their parents experienced various functional and psychosocial problems. However, there is insufficient knowledge regarding the impact of infantile esotropia as well as the effect of surgical correction towards the children and their parents.

**Objective:** To evaluate HRQoL assessment on pre- and post-strabismus surgery in children with infantile esotropia and their parent/guardian by using Malay translated IXTQ.

**Methodology:** This prospective study was conducted in Ophthalmology Clinics, Sabah Women and Children Hospital and Hospital Universiti Sains Malaysia from June 2017 until November 2018. The children and their parent/guardian were asked to answer Malay translated IXTQ at enrolment and three months after surgery. The total mean scores and three subscale scores which were functional, psychosocial and surgery, were calculated and compared before and after surgery.

**Result:** A total of 34 children with infantile esotropia aged 8-17 years accompanied by one of their parent/guardian were recruited. Thirteen (38.2%) children had esotropia more than 50 prism dioptres. Thirty three (97.1%) children achieved successful alignment correction. Strabismus surgery had significantly improved the total mean scores in children after surgery, which was 62.87 preoperatively and 87.13 postoperatively ( $p < 0.001$ ). There was statistically improvement in total mean scores in parent group, which was 37.07 preoperatively and 75.39 postoperatively ( $p < 0.001$ ). Its three subscales also had significant increment of the score postoperatively ( $p < 0.001$ ).

**Conclusion:** The mean scores of HRQoL assessment in children with infantile esotropia and their parents were improved significantly after strabismus surgery.



# CHAPTER 1

---

## INTRODUCTION

## **1.0 INTRODUCTION**

### **1.1 Infantile esotropia**

Infantile esotropia is a well-recognised disorder of ocular alignment where there is an inward turning of one or both eyes, commonly referred as crossed eyes. It occurs before the age of six months, with a constant, non-accomodative, large angle of strabismus (more than 30 prism dioptres), in the absence of nervous system disorder (Costenbader, 1961). Western population is reported to be more esotropia (Graham, 1974) while Asian population tends to have more exotropia (Yu et al., 2002; Matsuo et al., 2007). Esotropia is reported as 45.5% in United States (Friedman et al., 2009) while 12.5% in Singapore (Chia et al., 2010) and 7.1% in Malaysia among strabismic children (Teoh et al., 1982). Infantile esotropia accounts for 28-54% reported in United States (Louwagie et al., 2009) and 23% in Singapore (Chia et al., 2007).

The cause and risk factors associated with infantile esotropia are multifactorial. Worth et al. (1903) suggested there was an irreparable congenital defect in the infant's visual system and that surgery could be carried out at leisure mostly for cosmetic purposes. Chavasse et al. (1939) suggested a primary motor dysfunction, where the associated poor fusion and lack of high-grade stereopsis was probably a sensory adaptation to abnormal visual stimulation during early binocular development caused by the motor misalignment.

Major et al. (2007) revealed that risk factors such as prematurity, family history or secondary ocular history, perinatal or gestational complications, systemic disorders, use of supplemental oxygen as a neonate, use of systemic medications, and male sex were found to be significant for infantile esotropia.

Infantile esotropia is associated with mild amblyopia, small to moderate hyperopia, latent nystagmus, dissociated vertical deviation, limitation of abduction, and absent or reduced binocular vision (Costenbader, 1961). Infantile esotropia that persists beyond two years of age is associated with irrevocable stereoacuity deficits in essentially all patients (Birch et al., 2000). The goal of treatment of infantile esotropia is to align the visual axes to promote development of binocular vision.

Small to medium-angle esotropia can be treated nonsurgically by botulinum toxin (de Alba Compomanes et al., 2010) while for large-angle esotropia, surgical intervention is the mainstay of treatment (Lueder et al., 2012). Multiple surgeries may be needed to correct large angle esotropia. Amblyopia, residual esotropia or consecutive persistent exotropia may develop and should be addressed early to get the best possible visual and fusion potential. Early surgical correction is better as it is associated with improved stereoacuity outcomes and improved achievement of sensorimotor developmental milestone during infancy and thus improved long term quality of life (Hug, 2015).

## **1.2 Psychosocial effect of strabismus and surgery**

Strabismus in children leads to a wide range of physical and psychosocial problem which causes a serious and detrimental effect upon the child's health-related quality of life (HRQoL) as well as their parents. Children with strabismus are perceived more negatively for physical appearance, personality, and capability. These children have low self-esteem and feel embarrassed about themselves till unable to make eye contact with others and thereby interfering normal socialisation (Nelson et al., 2008). The age at which children may become aware of strabismus in others was studied by Paysee et al. (2001) who found that at approximately six years of age children began to express an overall negative response to playing with dolls with strabismus. Lukman et al. (2011) study revealed that school children were less willing to sit next to a person with noticeable exotropia which suggests that children with noticeable strabismus may be subjected to social alienation even at an early age.

Negative bias towards strabismus children is not only from peers but also from the teachers in school. Uretmen et al. (2003) showed that teachers also had major preconceptions regarding the performance of strabismic children. They preferred to assign school duties to "normal" children rather than strabismic children as the latter were believed to be less capable of fulfilling the assigned responsibilities. Furthermore, the study also revealed that esotropic children were perceived more negatively than exotropic children.

Social stigma persists into adulthood. Mojon-Azzi et al. (2008) found that people with strabismus were perceived to be less attractive, less interesting, less successful, and less intelligent than people without strabismus. Olitsky et al. (1999) and Coats et al. (2000) demonstrated that strabismus affected the ability to gain employment.

Strabismus is a type of chronic paediatric condition which has the potential to affect parental quality of life. A study by Akay and colleagues (2005) found that mothers of children with strabismus had more distress, dissatisfaction, and weaker family relationships than mothers of children without strabismus. The mothers were noticed failure to be an equalitarian and to be in a friendship relation with the child based on sharing. Strabismus creates a significant negative social prejudice and affects motherhood role.

Corrective surgery for strabismus is aimed to improve visual function by restoring binocular vision and removing the amblyopic stimulus caused by ocular misalignment. Studies have reported that strabismus surgery has improved quality of life functionally but also psychosocially. Mojon-Azzi et al. (2009) demonstrated adverse psychosocial impact associated with strabismus could be reduced with corrective surgery. Mruthyunjaya et al. (1996) found that surgical correction of strabismus in childhood was perceived by parents to be both successful and essential to them and their children.

Recent studies have shown corrective strabismus surgery significantly improved HRQoL score of children with strabismus as well as the parental score. Wang et al. (2015) conducted a prospective, randomised, parallel group study which involved 130 children with intermittent exotropia in China to undergo either corrective strabismus surgery or active monitoring without surgery. HRQoL of the children and their parents in both surgery group and control group were being assessed at enrolment and three months after intervention by using Intermittent Exotropia Questionnaire (IXTQ). The study demonstrated strabismus surgery had significantly improved all parts of IXTQ of child, proxy and parent.

Ziaei et al. (2016) showed that strabismus surgery improved physical and psychosocial function in children in Iran and children with greater amount of correction experienced more quality of life improvement after surgery. The prospective cohort study had recruited 87 children with congenital strabismus who scheduled for strabismus surgery. A modified version of RAND Health Insurance Study Quality of Life questionnaire was filled based on telephone interviews with parents before and three months after surgery.

Archer et al. (2005) performed a prospective interventional study which used a modified RAND Health Insurance Study Quality of Life questionnaire by telephone interview with the parents or guardians of 98 children with strabismus who planned for strabismus surgery at University of Michigan Kellogg Eye Centre. The telephone interviews conducted before and two months after corrective surgery. The study revealed strabismus surgery had significantly improved social, emotional and functional measures of the children's health status.

Another prospective interventional study was done by Chai et al. (2009) demonstrated strabismus surgery improved vision-related quality of life, anxiety and depression in China children aged below 15 years old. The study had enrolled 60 strabismic children who scheduled for strabismus surgery, and their parents were interviewed via telephone preoperatively and two months' postoperatively by using National Eye Institute Visual Functioning Questionnaire.

### **1.3 Health related quality of life**

Since 1980s, Health Related Quality of Life (HRQoL) studies were introduced to ophthalmology to explore the impact of disease on the overall quality of life on patients either physically or mentally. HRQoL questions have become a vital component of public health surveillance and are generally considered valid indicators of unmet needs and intervention outcomes. Self-assessed health status is also a more powerful predictor of mortality and morbidity than many objective measures of health. HRQoL measures make it possible to demonstrate scientifically the impact of health on quality of life (CDC, 2016). Different HRQoL questionnaires for strabismus have been developed lately to evaluate the quality of life for children and their parents.

### **1.4 Intermittent exotropia questionnaire**

The Intermittent Exotropia Questionnaire (IXTQ) is one of the child specific strabismus HRQoL questionnaires. It is a patient-derived, condition-specific questionnaire which specially designed to evaluate HRQoL in children with intermittent exotropia and their parents. It assesses the impact of exotropia on daily functioning, psychosocial interactions and possible surgery. The IXTQ consists of three parts which are child, proxy and parent IXTQ (Hatt et al., 2010). It can be used to assess children with a range of strabismus types as it seems to capture HRQoL information that appeared relevant to all persons with strabismus (Sim et al., 2014).



## **1.5 Rationale of study**

HRQoL in children with infantile esotropia is not sufficiently studied as there are not many strabismus-specific HRQoL assessment tools. Psychosocial effects of strabismus surgery have been studied in adults but not extensively in children and their parents. Furthermore, there is gap knowledge regarding HRQoL in Malaysia children with strabismus as well as their parents and the impact of strabismus surgery.

The purpose of this study is to evaluate strabismus surgery impact on HRQoL concerns of children with infantile esotropia as expressed by children and their parent in Malaysia population by using a validated Malay translated IXTQ (Tan and Shatriah, 2015 – unpublished data) and it can used as a reference for other regional studies in future.

# **CHAPTER 2**

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## **OBJECTIVES**

## **2.0 OBJECTIVES**

### **2.1 General objective**

To evaluate HRQoL assessment on pre- and post-strabismus surgery in children with infantile esotropia and their parents/guardians by using Malay translated IXTQ.

### **2.2 Specific objectives**

1. To compare the mean score of HRQoL assessment pre- and post-strabismus surgery in children with infantile esotropia by using Malay translated Child IXTQ.
2. To compare the mean score of HRQoL assessment pre- and post-strabismus surgery in parents or guardians of children with infantile esotropia by using Malay translated Parent IXTQ.

# CHAPTER 3

---

## METHODOLOGY

## **3.0 METHODOLOGY**

### **3.1 Study design**

This is a prospective study.

### **3.2 Population, place of study and duration of study**

#### **3.2.1 Study population**

All children aged 8 to 17 years old with infantile esotropia (untreated with surgery) and one of their parents/guardians who fulfilled the selection criteria, attended Ophthalmology Clinic in Sabah Women and Children Hospital, Kota Kinabalu and Hospital Universiti Sains Malaysia (USM) during the study period.

#### **3.2.2 Place of study**

Ophthalmology Clinics, Sabah Women and Children Hospital, Kota Kinabalu and Hospital USM.

#### **3.2.3 Duration of study**

This study was performed from June 2017 until November 2018.

### **3.3 Sampling and sample size**

#### **3.3.1 Sampling method**

Systematic random sampling method was carried out. Number 3 was randomly selected from number 1 to 5 as an interval in systematic random sampling. Thus, every 3<sup>rd</sup> children with infantile esotropia and one of their accompanying parents/guardians who attended Ophthalmology Clinics at Sabah Women and Children Hospital and Hospital USM that fulfilled both the inclusion and exclusion criterias were recruited.

#### **3.3.2 Sample size calculation**

Sample size calculation was done by using Power and Sample Size software using paired t-test formula. Effect size was set at 0.8 for each objective.

##### **3.3.2.1 Sample size calculation for Objective 1**

To compare the mean score of HRQoL assessment pre- and post-strabismus surgery in children with infantile esotropia by using Malay translated Child IXTQ.

$\sigma$  (standard deviation): 9.45 (Wang et al., 2015)

$\delta$  (difference in population means): 7

Power: 0.8

$\alpha$  (Type I error probability): 0.05

n (Total subjects required): 18

### 3.3.2.2 Sample size calculation for Objective 2

To compare the mean score of HRQoL assessment pre- and post-strabismus surgery in parents/guardians of children with infantile esotropia by using Malay translated Parent IXTQ.

$\sigma$  (standard deviation): 13.4 (Wang et al., 2015)

$\delta$  (difference in population means): 7

Power: 0.8

$\alpha$  (Type I error probability): 0.05

n (Total subjects required): 34

Based on the objectives, the final sample size determined for this study was **34** subjects in each group.

## **3.4 Selection criterias**

### **3.4.1 Inclusion criterias**

#### **3.4.1.1 Inclusion criterias for child**

1. Aged from 8 years old to 17 years old
2. Infantile esotropia
3. Normal anterior segment and fundus findings
4. Able to complete questionnaire and literate to Malay language

#### **3.4.1.2 Inclusion criterias for parent/guardian**

1. Parent/guardian of a child aged from 8 years old to 17 years old with infantile esotropia that fulfilled the inclusion and exclusion criterias
2. Able to complete questionnaire and literate to Malay language



### **3.4.2 Exclusion criterias**

#### **3.4.2.1 Exclusion criterias for child**

1. Previous strabismus surgery
2. Ocular diseases eg. cataract, glaucoma, retinal diseases
3. Neurological disorders eg. cranial nerve palsies, cerebral palsy
4. Associated craniofacial abnormalities and syndromes
5. Known developmental delayed or intellectual disability
6. Refused examination

#### **3.4.2.2 Exclusion criterias for parent/guardian**

1. Known intellectual disability
2. Known psychological illness prior to child's strabismus

### **3.5 Ethical approval**

This study was approved on 11<sup>th</sup> May 2017 by Medical Research and Ethics Committee (MREC) [reference number: NMRR-16-2555-32051] and on 5<sup>th</sup> July 2017 by Ethical Committee, School of Medical Sciences, USM [reference number: USM/JEPeM/17010070].

### **3.6 Financial support**

This study was not funded.

### **3.7 Definition of terms**

#### **3.7.1 Infantile esotropia**

Infantile esotropia is esotropia with an onset before the age of six months, with a constant, large angle of strabismus (more than 30 prism dioptres), in the absence of nervous system disorders (Costenbader, 1961).

#### **3.7.2 Strabismus surgery**

Surgical intervention is to align the visual axis to promote the development of binocular vision. The standard forms of surgical interventions in infantile esotropia include bilateral medial rectus recession, unilateral recession or resection, bilateral medial rectus recession with resection of one lateral rectus and bilateral recession or resection (Hug, 2015).

#### **3.7.3 Intermittent exotropia questionnaire**

Intermittent Exotropia Questionnaire (IXTQ) is a patient-derived, condition-specific questionnaire. It is designed purely to address concerns specific to children with intermittent exotropia and their parents. It assesses the impact of exotropia on the daily functioning, psychosocial interactions and possible surgery (Hatt et al., 2010).

#### **3.7.4 Likert type scale answer**

Likert type scale answer is a type of answer scales that allows the respondent to choose one of five degrees of feeling about a statement from strong approval to strong disapproval. It allows quantitative information about the survey subject.

### **3.8 Study tools and instruments**

- 3.8.1 Malay translated IXTQ
- 3.8.2 Snellen chart for distance visual acuity (Reichert, NY, USA)
- 3.8.3 Kay pictures acuity test (Kay Pictures Ltd, Hertfordshire, United Kingdom)
- 3.8.4 Smart system Optosmart
- 3.8.5 Fixation target for ocular motility assessment
- 3.8.6 Translucent eye occluder (Precision Vision, USA)
- 3.8.7 Luneau 22 block prism set (Luneau Technology, Chartres, France)
- 3.8.8 Frisby stereotest (Near) (Frisby Stereotest, Sheffield, UK)
- 3.8.9 Retinoscope (Keeler Ltd, Windsor, UK)
- 3.8.10 Retinoscopy trial lenses
- 3.8.11 Haag-Streit applanation tonometer (Clement Clark International, UK)
- 3.8.12 Air puff tonometer (Reichert, AT-555 auto non-contact pneumotonometer)
- 3.8.13 Slit lamp biomicroscopy (Clement Clark International, UK)
- 3.8.14 Binocular indirect ophthalmoscope (Heine, Germany)
- 3.8.15 90D, 78D, 20D and 28D lenses (Volk, USA)
- 3.8.16 Topical tropicamide (mydriacyl) 1.0% (Alcon-Couvreur, Puurs, Belgium)
- 3.8.17 Topical phenylephrine hydrochloride (mydfrin) 2.5% (Alcon Laboratories, INC., Fort Worth, Texas, USA)

- 3.8.18 Topical cyclopentolate (cyclogyl) 1.0% (Alcon-Couvreur, Puurs, Belgium)
- 3.8.19 Topical proparacaine hydrochloride (alcaine) 0.5% (Alcon-Couvreur, Puurs, Belgium)
- 3.8.20 Fluorescein sodium paper strip (fluorets) for ophthalmic use 1m (Bausch & Lomb, UK)



**Figure 3.1** Slit lamp biomicroscope



**Figure 3.2** Binocular indirect ophthalmoscope



**Figure 3.3** Goldmann applanation tonometer



**Figure 3.4** Airpuff tonometer



**Figure 3.5** a) Topical proparacaine  
 b) Topical tropicamide  
 c) Topical cyclopentolate  
 d) Topical phenylephrine  
 e) Fluorescein sodium paper strip

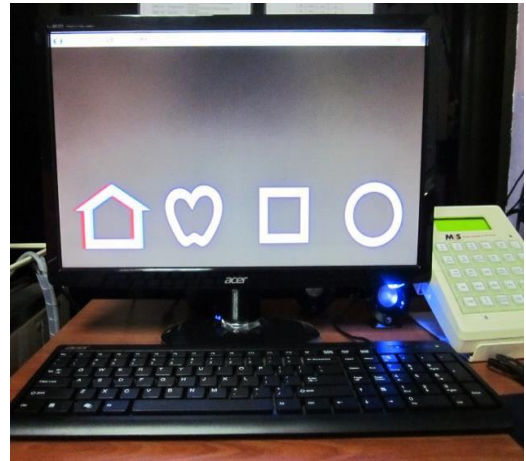


**Figure 3.6** Snellen chart





**Figure 3.7 Kay pictures acuity test**



**Figure 3.8 Smart system optosmart**



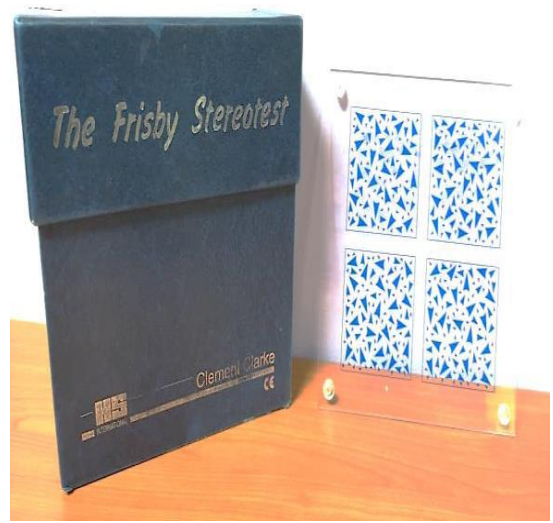
**Figure 3.9 Fixation target**



**Figure 3.10 Transparent occluder**



**Figure 3.11 Block prism set**



**Figure 3.12 Frisby stereotest**



**Figure 3.13 Retinoscopy trial lenses**



**Figure 3.14 Retinoscope**

### **3.8.1 Malay translated Intermittent Exotropia Questionnaire (IXTQ)**

The questionnaire was translated from English to Malay using standard procedure of forward and backward translation. Then the Malay translated version was assessed for internal reliability and content validation by Tan and Shatriah (2015).

The reliability of the questionnaire was justified by Cronbach's alpha value and the content validation was evaluated using content validity index (CVI). Both Cronbach's alpha value and CVI were satisfactory.

The Cronbach's alpha value for Malay translated IXTQ which obtained from Tan and Shatriah (2015) was 0.93 for Child IXTQ and 0.92 for Parent IXTQ (see appendix 8B, Table 8.1). Cook and Beckman (2006) mentioned that an instrument with Cronbach's alpha ranging from 0.60 to 0.99 was considered reliable to be used for studies.

Our study CVI value for Malay translated Child IXTQ was 0.99 and Parent IXTQ was 0.97 (see appendix 8B, Table 8.2 and 8.3). The CVI represented the assessment of relevance and representativeness of each questions in Malay translated IXTQ by six ophthalmologists in Hospital USM. Polit et al. (2007) recommended a tool which has I-CVIs of 0.78 or higher and an S-CVI/Ave of 0.90 or higher, was considered having good content validity.