

What makes thyroidectomy difficult: the thyroid, the patient or the surgeon?

Submission date 26/07/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 31/07/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 31/07/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The aim of this study is to assess the changes in heart rate of surgeons performing a thyroidectomy (surgery to remove the thyroid).

Who can participate?

Surgeons and their patients with benign thyroid disease who are undergoing thyroidectomy

What does the study involve?

During the surgery the surgeon completes a questionnaire and a small device is placed over their ear to measure their heart rate. This is non-invasive and does not interfere with the surgery.

What are the possible benefits and risks of participating?

This study is helpful for thyroid disease research and humanity. There may not be immediate benefits for the patients included in the study in terms of improving treatment. No cost will be paid to the patient for taking part in the study.

Where is the study run from?

Sanjay Gandhi Postgraduate Institute of Medical Sciences (India)

When is the study starting and how long is it expected to run for?

September 2016 to September 2018

Who is funding the study?

Sanjay Gandhi Postgraduate Institute of Medical Sciences (India)

Who is the main contact?

Dr Sabaretnam Mayilvaganan
drretnam@gmail.com

Contact information

Type(s)

Scientific

Contact name

Dr Sabaretnam Mayilvaganan

ORCID ID

<https://orcid.org/0000-0002-2621-394X>

Contact details

Raebareli Road

Lucknow

India

226014

+91 (0)9655851510

drretnam@gmail.com

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Use of modified thyroidectomy difficulty scale in thyroidectomy for benign thyroid diseases and surgeons stress during thyroidectomy

Acronym

TDTPS

Study objectives

1. To use the modified version of the thyroid difficulty scale validated in patients undergoing thyroidectomy (hemi or total) for benign thyroid disease to assess various factors contributing to difficult thyroidectomy
2. To calculate the metabolic rate as an indicator of stress and exertion during the procedure using heart rate (basal and maximum) of the surgeon
3. To use the anxiety stress index for the surgeon during surgery

Ethics approval required

Old ethics approval format

Ethics approval(s)

Sanjay Gandhi Postgraduate Institute of Medical Sciences Ethics Committee, 26/09/2016, ref: PGI/BE/549/2016

Study design

Observational study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Thyroid disorder

Interventions

The trialists have developed a 56-point modified Thyroidectomy difficulty scale, with 10 items with different grading for each item and its subvariables. This scale is based on the TDS developed by David S Schneider (permission to do so has been granted by him). A total of 50 patients undergoing total thyroidectomy for benign thyroid pathology would be included in the study.

Preoperatively the patient related factors i.e. the height, weight, neck length, comorbidities, preoperative laboratory results, would be recorded. Following the surgery pro forma for the modified TDS would be filled by the surgeon and the assistant within 6 hours of the procedure, blinded to each other's responses, so a total of 100 questionnaires would be analyzed. The minimum score of the modified TDS is 19 and maximum is 54. The higher the score more difficult the procedure is. The surgeon's baseline heart rate would be monitored throughout the procedure using a pulse oximeter probe, patented by Dr Ashish Kanujia (Dept of anaesthesia) that is OTG compatible. The probe would be placed over the ear lobule/pinna of the surgeon and connected to the android phone which can be comfortably placed in the surgeon's or the assistant's pocket inside the gown. An application (app) called USB SPO2, marketed by Berry, would be used for taking down the recordings. The pulse oximeter probe is small, soft, wearable and comfortable and is designed so as to not be obtrusive, giving full freedom to the surgeon/assistant. The graph would be analyzed and the heart rate fluctuations and the maximum heart rate during the surgery would be recorded. Metabolic rate of the surgeon/assistant would be calculated using the basal and the maximum heart rate. During periods of stress, as the heart rate increases, so does the metabolic rate, indicating the amount of exertion the surgeon undergoes during the procedure. The maximum heart rate that is allowed is given in terms of age, $[220 - \text{age}]$, and if the heart rate increases by more than 65%, it is an indicator of severe form of exertion. Anxiety stress index can also be calculated using the heart rate during the procedure. The patients included in the study would be followed up for a period of 6 months if they developed temporary or permanent complications, and the patients who were free of any complications would be followed till they are discharged from the hospital. The relationship between the TDS score and operative time, the relationship between TDS and operative complications, the TDS of the surgeon and the assistant would be compared and the inter-rater agreement would be evaluated.

Statistical Analysis

- Would be done using SPSS 15-0
- Non-parameter and parametric test applied as per data

Intervention Type

Other

Primary outcome(s)

The metabolic rate as an indicator of stress and exertion using heart rate (basal and maximum) of the surgeon during the procedure

Key secondary outcome(s)

The anxiety stress index for the surgeon calculated using heart rate during surgery

Completion date

01/09/2018

Eligibility**Key inclusion criteria**

1. Surgeons
2. Patients with benign thyroid diseases proven by cytology undergoing total thyroidectomy

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

On drugs

Date of first enrolment

01/09/2016

Date of final enrolment

01/09/2017

Locations**Countries of recruitment**

India

Study participating centre

Sanjay Gandhi Postgraduate Institute of Medical Sciences

Raebareli Road

Lucknow

India

226014

Sponsor information

Organisation

Sanjay Gandhi Postgraduate Institute of Medical Sciences

ROR

<https://ror.org/01rsgrz10>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Sanjay Gandhi Postgraduate Institute of Medical Sciences

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sabaretnam Mayilvaganan (drretnam@gmail.com)

IPD sharing plan summary

Available on request