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

Submission date
26/07/2018

Recruitment status
No longer recruiting

Registration date
31/07/2018

Overall study status
Completed

Last Edited
31/07/2018

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/09/2016

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

Age group
Adult

Sex
Both

Target number of participants
52

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
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/01rsgrz10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sanjay Gandhi Postgraduate Institute of Medical Sciences

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/09/2018

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