

THE INCIDENCE OF POST-OPERATIVE SORE THROAT IN BLOEMFONTEIN ACADEMIC HOSPITAL IN MAY-SEPTEMBER 2016

RESEARCH REPORT FOR MASTER'S DEGREE IN ANAESTHESIOLOGY

RESEARCHER: DR SP VUTHELA

STUDENT NO: 2003 083 462

SUPERVISOR: DR P DE WET

FORMAT : JOURNAL ARTICLE

DEPARTMENT OF ANAESTHESIOLOGY

UNIVERSITY OF THE FREE STATE

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1. DECLARATION OF OWN WORK

I hereby declare that the research paper titled THE INCIDENCE OF POST-OPERATIVE SORE THROAT IN BLOEMFONTEIN IN 2016 handed in by me (DR SP Vuthela) is based on actual and original work carried out by me. All references to work done by any institution, person or any material obtained duly cited and referenced. I further certify that the research paper has not been published or submitted for publication anywhere else.

2. ACKNOWLEDGEMENTS

I would like to pay special thanks and appreciation to the below mentioned people, who made my research a success and assisted me at different points during the course of my research:

Dr P De Wet (supervisor) for his support and guidance

Mr C Van Rooyen (statistician) for assistance with protocol and data analysis

To my **fellow colleagues** and **staff** at Bloemfontein Academic Hospital Complex who assisted with the collection of data for my study.

3. ABSTRACT

Background: Endotracheal intubation is frequently used during general anaesthesia to secure patients airway, prevent aspiration and to provide for positive pressure ventilation. Post operative sore throat is one of the many complications of endotracheal intubation.

Objectives: The aim of the study is to determine the incidence of post operative sore throat in Bloemfontein Academic Hospital Complex in healthy ASA 1 & 2 patient undergoing general anaesthesia.

Methods: In this *Prospective descriptive observational study*, 201 patients, aged 18-60 years, undergoing general anaesthesia (with ETT or LMA), for elective surgery in the Bloemfontein Academic Hospital Complex during May 2016 till September 2016 were included in the study.

Before induction of anaesthesia, the attending anaesthetist registrar or consultant obtained consent from the participants for the study. After the operation, the primary outcomes (Post-op sore throat) was assessed in the recovery room before discharge to the ward, in the ward at 2 and 6 hours post-op. Post operative sore throat was assessed on a 1-10 Verbal Numerical Pain scale where 1-3=*no sore throat*, 4-7=*significant sore throat* and 8-10=*Severe sore throat*.

Results: A total of 235 patients were enrolled in the study. 34 patients were excluded from the study, 16 were older than 60 years of age, 13 had emergency procedures and 5 incomplete data sheets. Data for 201 patients was analysed, in the **recovery room:** 51.24% of patients had no sore throat, 37.32% had significant sore throat and 11.4% had severe sore throat. **At 2 hours:** Post-Op, 78.6% had no sore throat, 19.4% had significant sore throat and 1.9% had severe sore throat. **At 6 hours:** 94% had no sore throat, 4% had significant sore throat and 2% had severe sore throat. Proportion of patients with hoarseness was 7.46%, 3.98% and 4.96% in the recovery room, at 2 and 6 hours respectively. The incidence of cough was 21.89%, 9.45% and 3% in the recovery room, at 2 and 6 hours post-op respectively.

Conclusion: Using a ten point numerical pain rating score, the incidence of post operative sore throat in our study was found to be 48.8% in the recovery room, 21.4% and 6% at 2 and 6 hours post-op respectively. Our study recommends that further studies should be done to determine if this sore throat leads to any morbidity or patients dissatisfaction and to explore measures that can be used to minimise sore throat post operatively.

4. ABBREVIATIONS & DEFINITIONS

POST : Post Operative Sore Throat

ET : Endotracheal Tube

LMA : Laryngeal Mask

URTI : Upper Respiratory Tract Infection

ASA : American Society of Anaesthesiologists (physical status classification)

1- A Normal Healthy patient

2-A patient with mild systemic disease

3-A patient with severe systemic disease

4-A patient with severe systemic disease posing constant threat to life

5-A moribund patient with who is not expected to survive without surgery

Post operative Sore throat pain score definitions

A ten point numerical rating score was used, where:

1-3= No pain

4-7= Significant sore throat

8-10=Severe sore throat

5. INTRODUCTION

Endotracheal intubation is a procedure used very frequently during general anaesthesia, its main aim is to maintain airway patency and provides for positive pressure ventilation with minimal risks of aspiration. The procedure entails placement of an endotracheal tube into the patient's trachea via the oral or nasal cavity using a laryngoscope.

Complications of endotracheal intubation include trauma to the lips, teeth, pharynx, vocal cords and trachea.¹ Sore throat is very common in the post operative period, in the literature reviewed the incidence of post operative sore throat (POST) was found to be 40-60% in healthy patients and as high as 60-80% in smokers.^{2;3}

POST incidence is high in the early hours post operatively and declines with time, with the highest peak at approximately 2-6 hrs post operatively. Case reports of POST lasting longer than 24hrs post extubation have been reported.^{4;5}

Postoperative sore throat has a multifactorial aetiology, and factors contributing to POST include female gender⁶, smoking⁷, intubation difficulty, suxamethonium use^{8;9}, high ET cuff pressures¹⁰, airway suctioning, long duration of surgery, laryngeal masks¹¹, mucosal injury with laryngoscopy, oropharyngeal airway and larger size ET-tubes.¹²

Irrespective of the cause, a sore throat manifests with irritating symptoms such as pain and irritation, most likely caused by inflammatory mediators, eg bradykinin and prostaglandins, which are released following local responses to cell damage and exert their effects on sensory nerves in the airways.

Sore throat is disturbing to patients, as it impacts negatively on patient's normal daily activities/functions such as eating, swallowing and talking. POST ranks as the 5-6th most common complaint post general anaesthetic, with surgical pain being on top of the list in recent studies.⁵

Modalities like anti-inflammatory drugs, analgesics and local anaesthetic sprays have been used to try and reduce the incidence of POST. Compared with oral analgesics treatments, topical remedies such as throat gargles¹³, sprays¹⁴, gel¹⁵, nebulisations¹⁶, intra cuff medication¹⁷ and lozenges¹⁸ which are applied directly onto the mucous membranes of the mouth and the throat, can provide more rapid symptomatic relief of the sore throat. There are differences between these delivery systems in the onset of action and the amount of the active ingredients present in the mouth or the throat. Throat sprays provide droplets into the throat and reach the desired target site. However, a proportion of the drug is swallowed immediately after administration, thus reducing the concentration of the delivered drug on the target sites. Evidence suggest that owing to the gargle reflex only the anterior wall of the throat receives the gargle and this makes gargles not effective in covering the sore throat from posterior throat¹⁸.

Lozenges are placed in the oral cavity and slowly dissolved to release their active ingredients directly onto the mouth walls and the pharyngeal walls. These offer an advantage of slow release of the drug, and their ease of use makes their administration preferable for patients.

In our institution we follow the conservative approach to post operative sore throat, we do not routinely use any of the above mentioned modalities to prevent sore throat. We also do not have any local literature quantifying the incidence of post operative sore throat in our institution.

6. AIM OF THE STUDY

The primary aim of the study is to determine the incidence of post operative sore throat in Bloemfontein Academic Hospital Complex in ASA 1 & 2 patient undergoing general anaesthesia.

Secondary aim of the study is to determine if our patients have the risk factors associated with Post Operative Sore Throat as stated in the literature.

7. METHODOLOGY

Study design

Prospective descriptive observational study

Sample/study participants

In the study we enrolled 235 patients undergoing general anaesthesia for elective surgery in the Bloemfontein Academic Hospital Complex during May 2016 till September 2016.

Inclusion criteria:

ASA 1/2 patients

Undergoing general anaesthesia for elective surgery

Ages of 18 to 60 years

Endotracheal intubation or

Laryngeal masks

Exclusion criteria:

ASA 3/4 Patients

Neck or throat surgery

Recent or Ongoing URTI

Use of Nasogastric tube

Use of Trans-oesophageal probe

Double lumen tubes

Existing sore throat pre-op

Patients who received sedating premedication on day of surgery

Emergency surgery

8. MEASUREMENT

Informed consent was obtained from participants by the attending anaesthetist on the day of surgery before induction of anaesthesia. Patients who received a sedating pre-medication were not included in the study, because they might not be able to give informed consent.

It was the responsibility of the attending anaesthetist (research assistant) to exclude or include patients in the study using the above criteria.

After the operation, the primary outcomes of the study were evaluated using a data sheet filled by a research assistant at three intervals:

1. In recovery room, before discharge to ward
2. In ward, at 2hrs post-op
3. In ward, at 6hrs post-op

Primary outcome: Post operative sore throat was assessed on a 1-10 Verbal Numerical Pain scale where;

1-3 = No pain

4-7 = Significant sore throat

8-10= Severe sore throat

Secondary outcome of the study was to determine if patients developed hoarseness and cough post operatively and also to determine if they have the risk factors associated with post operative sore throat that are described in the literature.

Patient's age, gender, race, nature of surgery, intubation technique, size and pressure in airway device, smoking status, and duration of surgery were also noted on the data sheet.

9. ANALYSIS

Descriptive statistics namely medians, means, standard deviations and percentiles were calculated for continuous data analysis. Frequencies and percentages were calculated for categorical data. The analysis was done by the Department of Biostatistics.

10. RESULTS

A total of 235 patients were enrolled into the study, 34 patients were excluded. 16 patients were older than 60 years, 13 had emergency surgery and 5 had incomplete data sheets. In total 201 patients data was analysed for the study. Mean age for participants was 41 (18-60), with a mean weight of 80kgs (48-130). Most patients were of black race 48% (n=97) and the majority of patients are males 54% (n=110). (Table 1 below summarises patient demographic data).

Variable	number	Mean
age	201	41
Weight	201	80
Height	201	169
Race	Frequency	Percent
Black	97	48.26
White	77	38.31
Coloured	27	13.43
Gender		
Male	110	54.7
Female	91	45.3

The variables associated with post operative sore throat are summarized in **table 2** below. 39.8% (n=80) of participants were not smoking. The mean duration of surgery was 110min (18-315) and most patients airway was managed by the attending registrar 81% (n=163). Rapid sequence induction was only done in 19,6% (n=30). Airway management was considered to be difficult in 4.57% (n=11) of patients. With 91% (n=184) of the patients, the airway was successfully secured at first attempt. In 17 patients, 2 (n=14), 3 (n=1) and 4 (n=2) attempts were used to secure the airway.

Endotracheal intubation (ETT) was used to secure the airway in 153 patients, with Laryngeal Masks (LMA) used in 48 patients. ETT tubes used were of size 7-8.0mm internal diameter, while the LMAs were size 3-5. The mean cuff pressure in the ETT was 27.66 (10-30) cm.H₂O and 57.75 (35-70) cm.H₂O for LMAs. Size 4 LMA was the most commonly used LMA (64.58%). The three ETT sizes were used at similar frequencies i.e size 7.0 (33.9%), 7.5 (30%) and 8(35.9%).

Table 2:

POST-OP SORE THROAT RISK FACTORS			Sore throat %		
Smoking	Frequency	Percent	None	Significant	Severe
Yes	80	39.8	34	55	11
No	121	60.2	48	37	15
Duration of surgery (min)					
Number	Mean	Std Dev.			
201	110	58			
Anaesthetist	Frequency	Percent			
Intern	36	17.91	61	35	4
Registrar	163	81.09	50	38	12
Consultant	2	1	50	50	0
RSI	Frequency	Percent			
Yes	30	19.6	44	41	15
No	123	80.4	57	32	11
Difficulty	Frequency	Percent			
Yes	11	5.47	20	55	15
No	190	94.53	33	53	14
Attempts	Frequency	Percent			
1	184	91.54	28	45	17
2	14	6.97	45	39	16
3	1	0.5	0	100	0
4	2	1	50	50	0
ETT size	Frequency	Percent			
7	52	33.99	54	34	12
7.5	46	30.07	28	56	16
8	55	35.95	48	36	16
ETT Cuff Pressure (cm-H ₂ O)					
N	Mean	Std Dev			
153	27.66	2.79			
LMA size	Frequency	Percent			
3	3	6.25	33	33	33
4	31	64.58	55	24	21
5	14	29.17	51	32	17
LMA cuff pressure (cm-H ₂ O)					
N	Mean	Std Dev			
48	57.75	9.33			

Most patients were operated by general surgery (22%), Orthopaedics (19%) and Gynaecology (15%) as outlined in Figure 1.

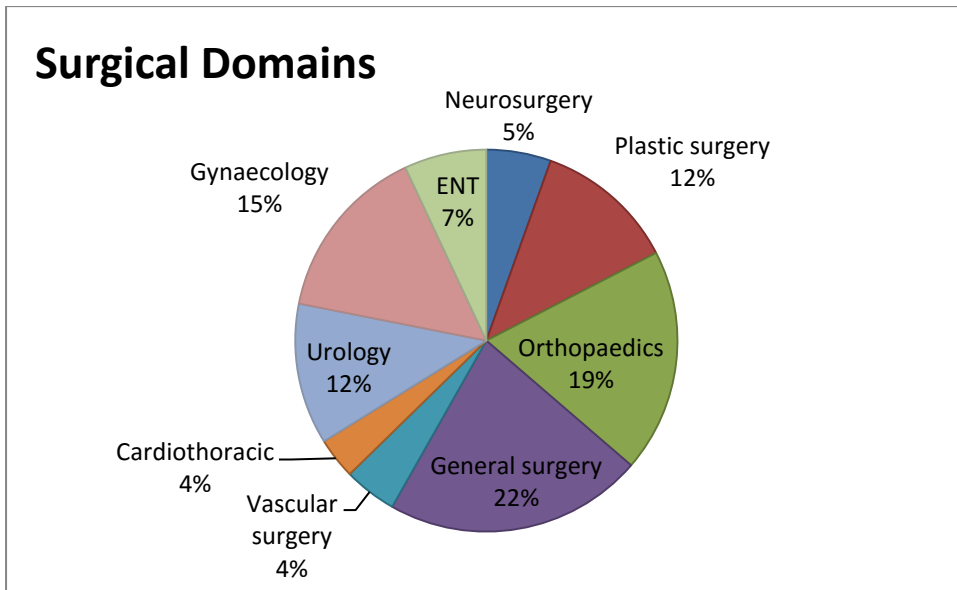


Figure 1: Surgical theatres that operated the patients

A “1-10” Numerical Pain Scoring system was used to grade the degree of post-op sore throat, where 1-3= *No sore throat*, 4-7= *Significant sore throat* and 8-10= *Severe Sore Throat*. **Figure 2:** Below demonstrates that 51% of patients had no sore throat in the recovery room, 37% had significant sore throat and 11% had severe sore throat.

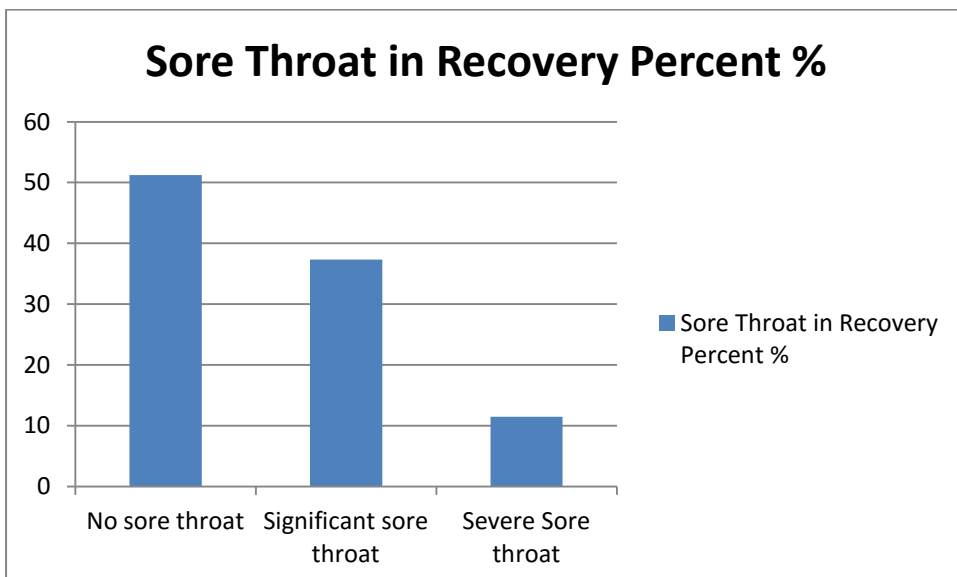


Figure 2: Sore Throat in the Recovery Room

In **Figure 3**: 2 hours Post-op, 78.6% of patients had no sore throat, 19% had significant sore throat and 1.98% had severe sore throat.

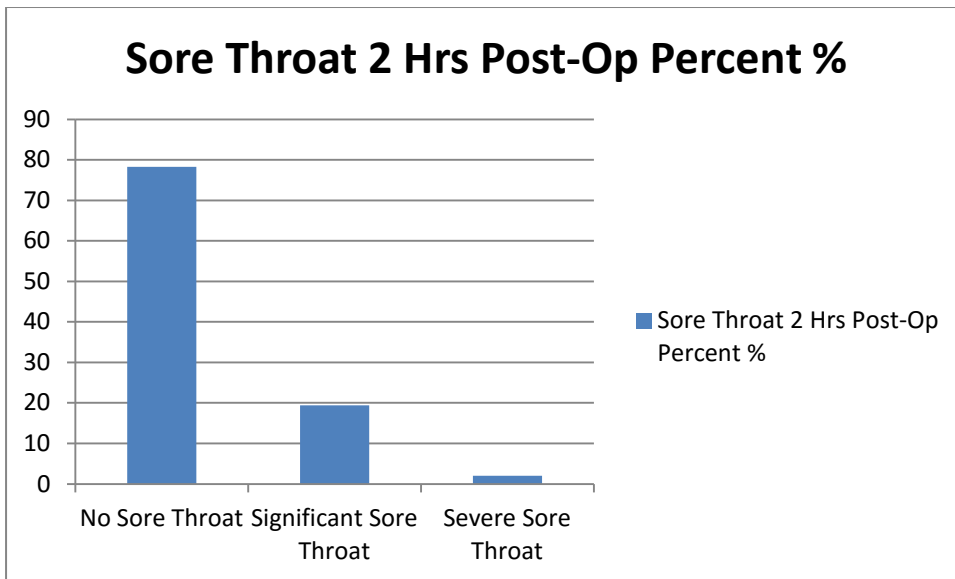


Figure 3: Sore Throat 2 Hrs Post-op

In **Figure 4 below**: 6 Hours Post-OP, 94%of patients had no sore throat, 4% had significant sore throat and 2% had severe sore throat.

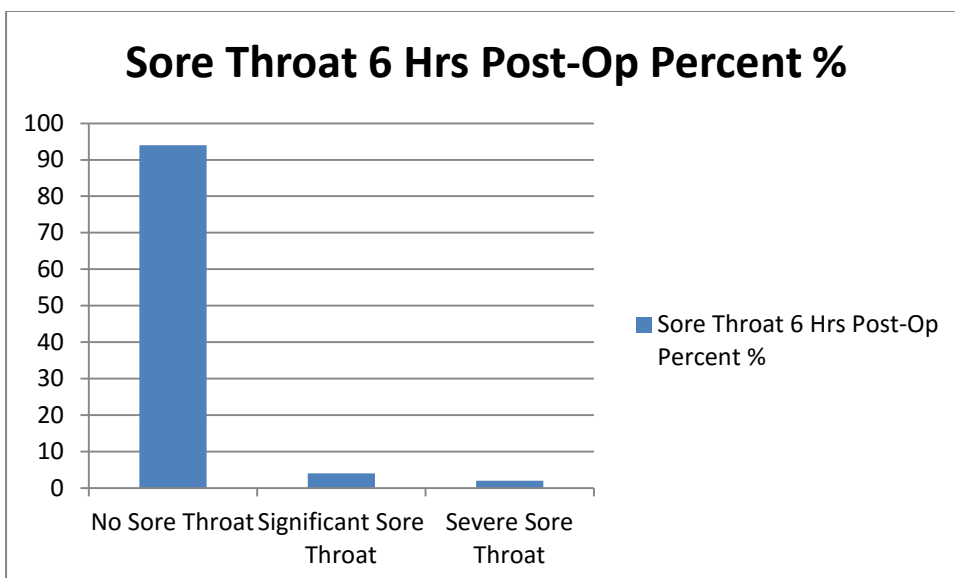


Figure 4: Sore throat 6 Hrs Post-op

Figure 5 Below, demonstrates a chart with the three incidences of Post-op Sore Throat from the recovery room to 2 and 6 hours post-op. It is clear from the three charts that a significant proportion of participants had no pain versus those who had significant and severe sore throat. The results also demonstrate that Post-Op sore throat is higher in the recovery room 49% and declined to 21% and 6% at 2 and 6 hours post-op respectively.

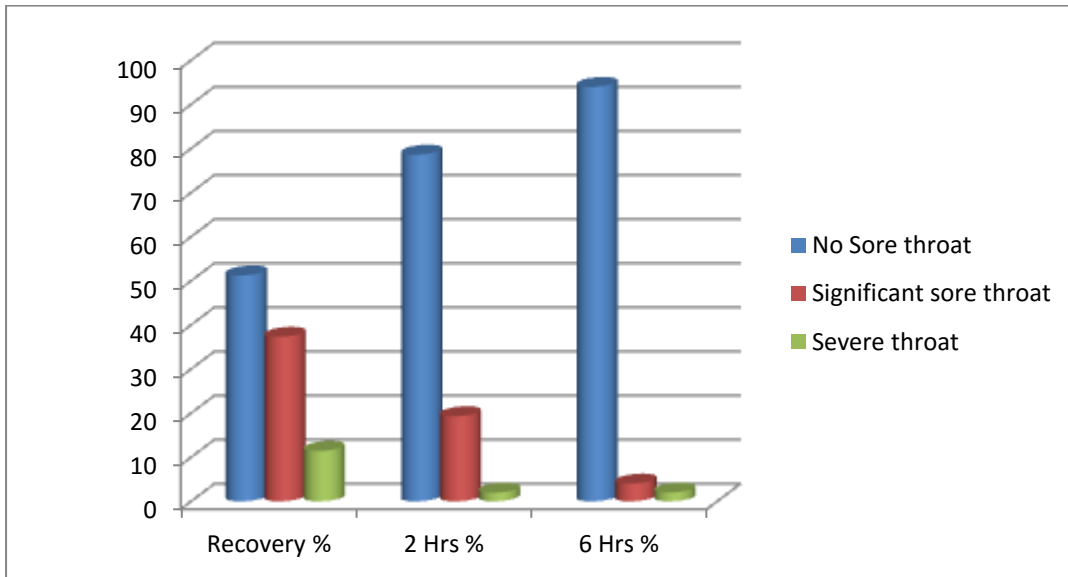


Figure 5: Incidence of Post operative sore throat

In **Figure 6** Below: The percentage of patients who developed Hoarseness Post-op is plotted at 3 different times. In the recovery room 7.46% (n=15) had hoarseness, while at 2 and 6 hours the percentage was 3.98% (n=8) and 4.98% (n=10) respectively.

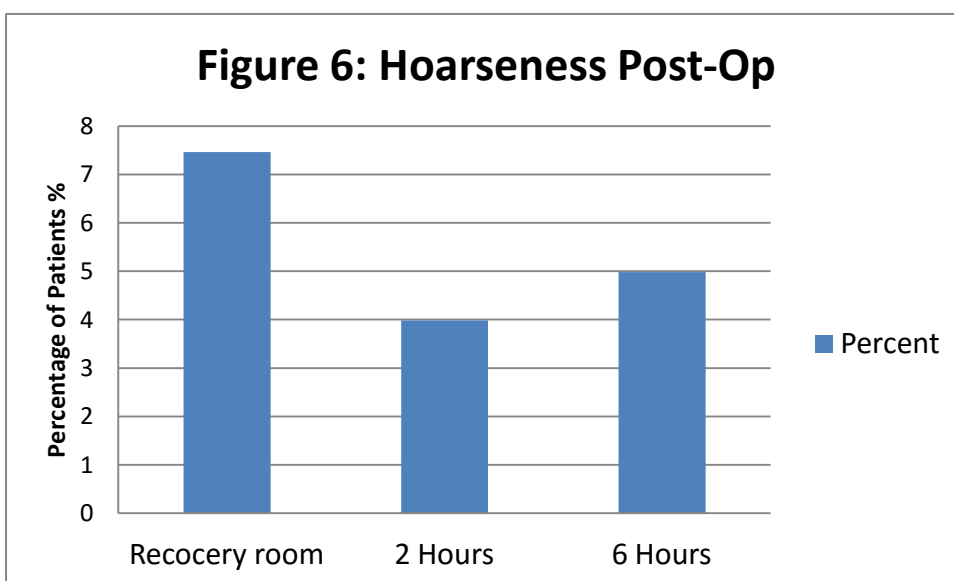
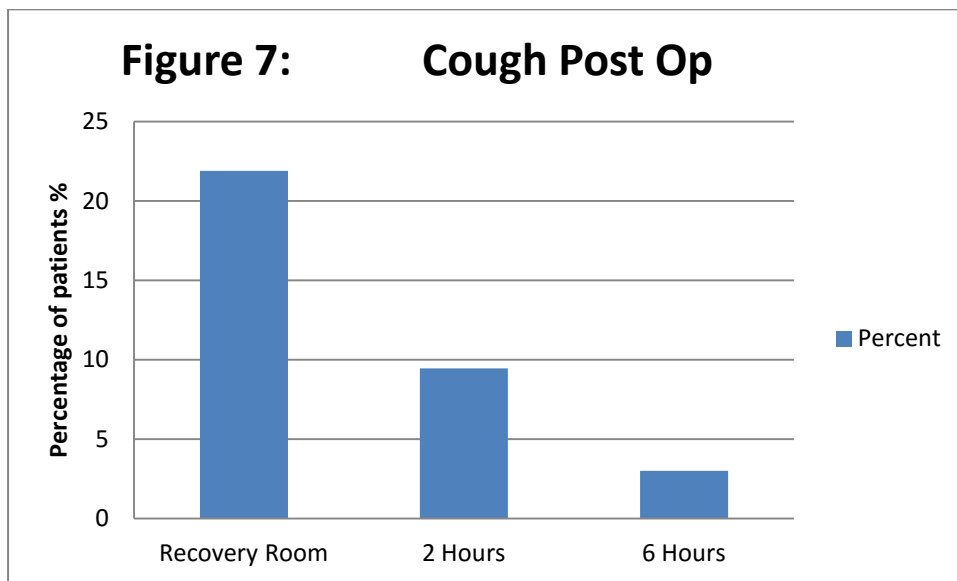


Figure 7: Demonstrates a graph plotting the percentage of patients who developed a Cough post-operatively. In the recovery room 22% (n=44) of patients developed a Cough, and at 2 and 6 hours 9.45% (19) and 3% (6) respectively.



11. DISCUSSION

In a prospective observational study done by Ahmed. A and et al, in 2007 the Incidence Post Operative Sore throat was 26% in a study population of 312 patients undergoing elective surgical procedures.²¹ 28% of patients with Endotracheal Intubation (ETT) and 3.5% of patients with LMAs had Post Operative Sore Throat. A study done by P.P Higgins, et al in 2002, 5264 who had ambulatory surgery had postoperative sore throat incidence of 12.1%, patients who had ETT had incidence of 45.4%, followed by LMA with incidence of 17.5%, while face mask patients had incidence the lowest incident of sore throat, 3.3%.²²

In our study we evaluated the incidence of POST at three intervals (i.e in recovery room, in the ward at 2 and 6 hours) in the post operative period, in contrast to the above studies were it was measured at only one point at 24 hours Post op. The incidence of postoperative sore throat in our study was 49% in the recovery room, 21% at 2 hours and 6% at 6 hours in the ward. 153 patients were intubated and 48 had LMAs, the incidence of POST in the intubated group was 38% (recovery room), 11% (2 hours) and 3% (6 hours). With the 48 patients that had LMAs the POST incidence was 8.5% (recovery room), 4.2% (2 hours) and 1.1% (6 hours). The incidences of post operative sore throat in our study were different in contrast to the studies done by Higgins and Ahmed as outlined above. The explanation for this might be because of the different measurement times as they only measured at a single point at 24 hours post operatively. They also do not describe what rating scale they used or which score they regarded as significant sore throat.

31 (15%) patients from the total population of 201 patients complained of severe sore throat, 14 (45%) of them had laparotomy for various operations and the procedures lasted for more than 2 hours. Of note in these 31 patients was that 20 (65%) were females. Rapid sequence induction

technique was used in 15% of these patients and the cuff pressure in the ETT ranged from 25-30cm.H₂O. The ETT size frequently in this group was size 7.5mm [23 (74%)], 8mm in [7 (22%)] and 7mm in [2(6%)]. Only 2 patients had intubation attempts of more than once and were classified as having difficult airway management. Different attending registrars intubated all these 31 patients. 24 (78%) were of Caucasian race and 10 were smokers (43%). At 6 hours postoperatively all these 31 patients had Sore throat score of less than 3/10, which shows the nature of POST to recover with time. This might be attributed to the use of pain medication in the post-operative period for the management of surgical site pain as none of them received any of the treatment modalities described in the literature for POST. Hoarseness and cough was only reported by 3 (9.6%) patients in this group of patients, which also subsided with time after surgery. The incidence of sore throat in the smoking patients was 66%, compared to only 52% in the non-smoking participants.

Limitations of our study are that we measured sore throat at three intervals as the patient recovered from anaesthesia and surgery, as opposed to once at 24 hours after surgery. Due logistics around human resources we limited our study to only 6 hours post-operatively, however we found the incidence to be high in the recovery room 49% and declined with time to 6% at 6 hours in the ward. It would have been interesting to see what the incidence would be at 24 hours like in the previously mentioned studies. The significance and morbidity of this postoperative sore throat was not assessed by our study. Our study did not take into account what medications the participants received peri-operatively. We are not aware of how the effects of anaesthesia and surgery would influence patient's responses to direct questioning during data collection from the recovery room to the ward. On our data sheets we failed to include the design of airway device, the design and make of endotracheal tubes and LMAs has evolved over the year to improve comfort and ease of use. In our institution we use HME filters in our anaesthetic circuits provided we have stock available, it would have been interesting to find out if this had an influence in our study. The aim of our study was mainly to assess what the incidence of postoperative sore throat is in our institution with our current anaesthetic practices.

In conclusion, the Incidence Postoperative Sore Throat in our institution is 49% in the recovery room, 21.4% at 2 hours and 6% at 6 hours postoperatively in patients undergoing elective surgery. Our study demonstrates that the postoperative sore throat incidence declines with time, we recommend that further studies should be done to determine if this sore throat leads to any morbidity or patients dissatisfaction and to explore measures that can be used to minimise sore throat post operatively.

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13. Appendices

APPENDIX A: INFORMED CONSENT

Title of the study

Incidence of Post-Operative Sore Throat in Bloemfontein Academic Hospital Complex in 2016

Purpose of the study

Is to determine the incidence of post operative sore throat on patients undergoing general anaesthesia for elective surgery in Bloemfontein Academic Hospital Complex in 2016

Duration of the study

May to September 2016

Potential advantages of the study

The outcomes of the study might help raise awareness regarding the incidence of post operative sore throat and possibly indicate if there is a need for a change in the practices to prevent and manage this common complaint as found in other studies.

Side effects for the patient

The study poses no side effects on the patients since there will be no medication or intervention given to the patients.

Voluntary participation

Participation and exit from this study is completely voluntary, no patient will be coerced into participating in this study.

Procedure

You will be asked if you have sore throat, hoarseness or cough at three intervals after the operation, namely:

1. Before discharge to the ward
2. At 2 hours and 6 hours after the operation in the ward

Time it takes to participate in the study

The questioning will take less than 5 minutes at each interval

Confidentiality

Patient information will be kept strictly confidential during data collection, analysis of the results and after the study. You will remain anonymous in the study. The consent form will have your name and signature to show you gave consent but will not be connected to the data sheet.

Publication of the results

The research will be submitted for M.med and our hope is to publish the results of this study in a suitable journal of anaesthesia upon its completion

Remuneration of participants

Unfortunately there will be **no** remuneration for participation in this study

Contact persons

Researchers

Dr SP Vuthela 082 5107 385 email: pvuthela@gmail.com

Dr P De Wet 083 384 9829 email: drpieterdewet@hotmail.com

I (Name and Surname).....have read, understand and give consent to participate in this study.

Signature:

Date:/...../.....

APPENDIX B: PARTICIPANT INFORMATION

You are kindly asked to participate in the research study outlined below

Title of study

Incidence of Post-Operative Sore Throat in the Bloemfontein Academic Hospital Complex in 2016

Purpose of the study

Is to determine the number of patients who wake up with a sore throat after undergoing general (sleeping) anaesthesia for elective (non-urgent) surgery in Bloemfontein Academic Hospital Complex in 2016

Type of study

Observational descriptive study (no intervention done/given to participants)

Duration of the study

May to September 2016

Procedure/Methods

On the morning of your scheduled surgery in theatre, the attending anaesthetist (research assistant) will obtain informed consent from participants and go through the inclusion and exclusions criteria for the study. The scheduled surgery and anaesthesia will be carried out as planned with the patient by the surgeon and the anaesthetist.

Participants included in the study will be asked by a research assistant if they have sore throat, hoarseness or cough at three intervals after the operation, namely:

1. In the recovery room, before discharge to the ward
2. At 2 hours and
3. 6 hours after the operation in the ward

Sore throat will be graded on a scale of 1-10 by the participants, where 1-3= *No Sore throat*, 4-7 *Significant sore throat* and 8-10= *Severe sore throat*

Potential advantages of the study

The outcomes of the study might help raise awareness regarding the number of patients waking up with sore throat after operations and possibly indicate if there is a need for a change in the practices to prevent and manage this common complaint as found in other studies.

Side effects for the patient

The study poses no side effects on the patients since there will be no medication or intervention given to the patients.

Voluntary participation

Participation and exit from this study is completely voluntary, no patient will be coerced into participating in this study.

Confidentiality

You will remain anonymous and your information will be treated confidentially at all times

Publication of the results

The research will be submitted for M.med and our hope is to publish the results of this study in a suitable journal of anaesthesia upon its completion

Appendix C: Foromo ya Tumellano ka Kutlwisiso

Taetlele ya dipatlisiso

Dipalopalo tsa batho ba tsohang ba tshwere ke mmetso o bohloko ka mora ho robatswa bakeng sa o etswa oporeishini Sepetleleng sa Bloemfontein Academic Hospital Complex selemong sa 2016.

Maikemisetso a dipatlisiso

Ke ho batlisisa dipalopalo tsa batho ba tsohang ba tshwere ke mmetso o bohloko ka mora ho robatswa madimong (theatre), Sepetleleng sa Bloemfontein Academic Hospital Complex selemong sa 2016.

Nako eo dipatlisiso di tla etsahalang ka yona

Mmesa 2016 ho fihla ka Lwetse 2016

Molemo wa dipatlisiso

Dipatlisiso tsena di tla thusa ho etsa barobatsi be tsebe hore na bakudi ba robatswang ba tsoha bana le mmetso o bohloko kapa tjhee, hona ho tla lemohisa barobatsi hore mohlomong ho hloka hore ba etse ho hohong ho thibela bohloko bona ba mmetso ha bakudi ba tsoha.

Ditlamoraho tsa dipatlisiso

Hahona ditla morao tse kabang teng ho bakudi ba nang le seabe dipatlisisong tsena hobane hahona sesebediswa se tla sebediswang dipatlisisong tsena.

Seabe dipatlisisong

Bakudi bohle ba nang le seabe dipatlisisong tsena ba dumelletse ho kena le hotswa dipatlisisong tsena nako e feng kapa efeng ntle le tshutsumeyo ya motho.

Ditsamaiso

Ka mora operesishine ha mokudi a se a tsohile o tla botswa dipotso hore na ebe o na le mmetso o bohloko, ho kgohlela kapa lentswe le cheleng. Dipotso di tla botswa ha raro:

1. Pele mokudi a tloha madimong hoya kamoreng ya bakudi
2. Ka mora hora tse pedi
3. Ka mora hora tse tshelletseng

Nako ya ho araba dipotso

Nako ya ho araba dipotso e tla ba ka tlase ho metsoso e mehlano

Sephiri dipatlisisong

Ditaba tsa bakudi di tla tshwarwa ka maemo a hodimo le siphiri ka nako tsohle, ho tloha qalong hoya qetellong ya dipatlisiso tsena. Bakudi ha bano tsebahala hore ba ile ba fana ka dikarabo difeng haho rarollwa di diphetoho tsa dipatlisiso. Mabitso a bakudi a tla hlahella foromong ena ya tumellano feela, ele ho paka hore ba ile ba fana ka tumellano ho kenela dipatlisiso tsena.

Phatlalatso ya sepheto sa dipatlisiso

Sepheho sa dipatlisiso tsena di tla romelwa Universiting ya Foreisitata jwalo ka dipatlisiso tsa sekolo sa borobatsi, mme di phatlalatswe dikoranteng tsa dingaka tsa barobatsi tse tla kgethuwa ke baphatlalatsi.

Moputso

Ka maswabi ha ho moputso o tla fuwa bakudi ba bang le seabe dipatlisisong tsena.

Ba batlisisi

Ngaka SP Vuthela 082 5107 385 pvuthela@gmail.com

Ngaka P De Wet 083 384 9829 drpieterdewet@hotmail.com

Nna (Lebitso le Sefane) ke badile, ke utlwisisa le ho fana ka tumellano ho ba le seabe dipatlisisong tsena.

Tshaeno (signature):.....

Letsatsi (date):...../...../.....

APPENDIX D: DATA COLLECTION QUESTIONNAIRE

INSTRUCTIONS

MARK WITH AN X OR WRITE IN THE ALLOCATED AREA

1. DATE OF SURGERY: (dd/m/yr)...../...../.....

3. AGE OF THE PATIENT: (yr).....yr

4. Gender:

3. PATIENT'S RACE

1	BLACK
2	WHITE
3	COLOURED
4	ASIAN
5	INDIAN
6	OTHER

4. WEIGHT (Kgs):kgs

5. HEIGHT (cm):cm

6. PRE-OP DIAGNOSIS :

7. PROPOSED SURGERY:

08.TIME OF ANAESTHESIA INDUCTION:.....H.....

09. END OF SURGERY TIME:.....H.....

SORE THROAT RISK FACTORS

10. ETT INTUBATION

11.1 SKILL

1	STUDENT	
2	REGISTRAR	
3	CONSULTANT	

11.2 RSI

1	YES
2	NO

FOR OFFICE USE	
-----------------------	--

			1-3
--	--	--	-----

						4-9
--	--	--	--	--	--	-----

		10-11
--	--	-------

		12-13
--	--	-------

			14-16
--	--	--	-------

			17-19
--	--	--	-------

		20-21
--	--	-------

		22-23
--	--	-------

				24-27
--	--	--	--	-------

				28-31
--	--	--	--	-------

	32
--	----

	33
--	----

11.3 DIFFICULT

1	YES
2	NO

11.4 ATTEMPTS

11.5 ETT SIZE

11.6 CUFF PRESSURE

	cmH ₂ O
--	--------------------

	34
--	----

	35
--	----

	36
--	----

		37-38
--	--	-------

11.
LMA

LMA SIZE

--

LMA CUFF PRESSURE

	cmH ₂ O
--	--------------------

	39
--	----

		40-41
--	--	-------

12.
SMOKING

1	YES
2	NO

	42
--	----

13. POST-OP SORE THROAT: **VERBAL 10 POINT SCALE**
WHERE "1" IS **NONE** AND "10" IS **THE WORST SORE THROAT**
MARK WITH "X"

	RECOVERY	2 HRS	6 HRS
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

			43-45
--	--	--	-------

14. HOARSENESS

		RECOVERY		2 HRS		6 HRS
1	YES		YES		YES	
2	NO		NO		NO	

			46-49
--	--	--	-------

15. COUGH

		RECOVERY		2 HRS		6HRS
1	YES		YES		YES	
2	NO		NO		NO	

			50-52
--	--	--	-------

APPENDIX E: PROTOCOL SUMMARY

Purpose of the study

Is to determine the incidence of post operative sore throat on patients undergoing general anaesthesia for elective surgery in Bloemfontein Academic Hospital Complex in 2016

Type of study

Observational descriptive study (no intervention)

Duration of the study

May to September 2016

Procedure/Methods

On the morning of scheduled surgery in theatre the attending anaesthetist (research assistant) will obtain consent from participants and go through the inclusion and exclusions criteria for the study. The scheduled surgery and anaesthesia will be carried out as planned with the patient by the surgeon and the anaesthetist.

Participants included in the study will be asked by a research assistant if they have sore throat, hoarseness or cough at three intervals after the operation, namely:

4. In the recovery room, before discharge to the ward
5. At 2 hours and
6. 6 hours after the operation in the ward

Sore throat will be graded on a scale of 1-10 by the participants, where 1-3= *no sore throat*, 4-7= *Significant sore throat* and 8-10 is *severe sore throat*

Potential advantages of the study

The outcomes of the study might help raise awareness regarding the incidence of post operative sore throat and possibly indicate if there is a need for a change in the practices to prevent and manage this common complaint as found in other studies.

Side effects for the patient

The study poses no side effects on the patients since there will be no medication or intervention given to the patients.

Voluntary participation

Participation and exit from this study is completely voluntary, no patient will be coerced into participating in this study.

Confidentiality

Patient information will be kept strictly confidential during data collection, analyses of the results and after the study

Publication of the results

The research will be submitted for M.med research and our hope is to publish the results of this study in a suitable journal of anaesthesia upon its completion

Remuneration of participants

Unfortunately there will be **no** remuneration for participation in this study

Contact persons

Researchers

Dr SP Vuthela 082 5107 385 email: pvuthela@gmail.com

Dr P De wet 083 384 9829 email: drpieterdewet@hotmail.com

APPENDIX F: BIOSTATISTICS APPROVAL



25 January 2016

For attention: Ethics Committee
Faculty of Health Sciences

**Title of project: Incidence of Post-operative Sore Throat in Bloemfontein
Academic Hospital Complex**

Researcher:

Dr SP Vuthela

I hereby confirm that I approve of the study design, sampling method, measurement,
and statistical analysis of the above-mentioned protocol.

Yours faithfully

FC van Rooyen

A handwritten signature in black ink, appearing to read 'F. van Rooyen'.



APPENDIX G:

Authorities letter of approval for an M.med Anaesthesiology Research

Topic

The incidence of Post Operative Sore Throat in patients undergoing elective surgery under general anaesthesia in Bloemfontein Academic Hospital Complex in 2016

Methodology

Observational descriptive study

Duration of the study

March 2016 to September 2016

Researchers: Dr SP Vuthela
DR P DE Wet (study leader)

Anaesthesiology Dept. HOD

Name: *J. S. Diedericks*
Signature: *[Handwritten Signature]*
Date: *25/11/16*

Hospital CEO

Name:.....
Signature:.....
Date:...../...../.....

Please find attached the research protocol and relevant documents for ethics committee approval

APPENDIX H: ETHICS COMMITTEE APPROVAL



IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

20 April 2016

DR SP VUTHELA
DEPT OF ANAESTHESIA
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr Vuthela

HSREC 35/2016

PROJECT TITLE: INCIDENCE OF POST OPERATIVE SORE THROAT IN BLOEMFONTEIN ACADEMIC HOSPITAL COMPLEX IN 2016

1. You are hereby kindly informed that, at the meeting held on 19 April 2016, the Health Sciences Research Ethics Committee (HSREC) approved the above project after all conditions were met.
2. The Committee must be informed of any serious adverse event and/or termination of the study.
3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.
4. A progress report should be submitted within one year of approval and annually for long term studies.
5. A final report should be submitted at the completion of the study.
6. Kindly use the **HSREC NR** as reference in correspondence to the HSREC Secretariat.
7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act, No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes [2015]; SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

DR SM LE GRANGE
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

