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Paediatric dental chair Procedural Sedation and Analgesia: A follow up study.

By Thomas Tarlton

Student Number: A0041634

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology.

Johannesburg, 2024

Declaration

I, Thomas Mark Tarlton, declare that this research report is my own unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



_____ _20-08-2024_____

Signature Date

Abstract

Background

The South African Society of Anaesthesiologists (SASA) paediatric procedural sedation and analgesia (PSA) guidelines provide instructions for the safe administration of paediatric PSA and the management of complications. The pilot study found a lack of adherence to the recommended safety standards among dentists in Gauteng. The departments of Anaesthesiology and Dental Science at Wits placed emphasis on “safe sedation principles” with the intention that greater awareness of the guidelines may result in improved guideline adherence.

Aim

The aim of this study is to determine if there has been a change in paediatric dental chair PSA practice and guideline adherence among Wits BDS graduates, after the publication of “Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa” in 2015.

Methods

A prospective, contextual, descriptive survey study design was used. The survey was adapted from the pilot study to define the current practice of paediatric dental chair PSA among Wits BDS graduates and determine the level of guideline adherence. The findings of the pilot and follow up studies were compared.

Results

The study found that 62% of dentists had no sedation training. Sixty-six percent of sedation practitioners working for dentists were sedation trained medical practitioners or anaesthetists. Twenty-two percent of dentists continue to perform the role of operator and sedation practitioner simultaneously.

There remains a lack of paediatric PSA guideline adherence despite improvements in the following areas: documentation of written informed consent; implementation of fasting guidelines; use of monitoring equipment, use of staffed recovery areas and availability of emergency drugs and equipment.

The proportion procedures performed under deep sedation and general anaesthesia increased as did the number of sedation related complications. The most common complications were oxygen desaturation (62%), airway obstruction (38%) and apnoea (19%). No cardiac arrest or deaths were reported.

Conclusion

The follow up study found a lack of paediatric PSA guideline awareness and unsafe practice of paediatric dental chair PSA among Wits BDS graduates from 2016 to 2021. The study has highlighted a need for postgraduate accredited sedation training and the ongoing audit of paediatric dental chair PSA.

Acknowledgements

As the author, I would like to thank the following people for their contribution.

To Dr Christopher Anamourlis and Dr Faizal Bham, I thank you for your time, supervision and guidance. Your assistance has been greatly appreciated.

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To my wife, Joy, and family, thank you for your overwhelming love and encouragement.

Table of Contents

Declaration i

Abstract ii

Acknowledgements iii

List of Figures vi

List of Abbreviations vii

Statement viii

Section 1: Literature review 9

1.1 Introduction 9

1.2 References 13

Section 2: Author's guidelines 15

Section 3: Draft Article 30

Abstract 31

Introduction 32

Methods 32

Results 33

Unchanged variables ..... **Error! Bookmark not defined.**

Changed variables. ..... **Error! Bookmark not defined.**

Discussion 49

Conclusion 54

Section 4: Proposal 58

Section 5. Annexures 88

5.1 Ethics approval 88

5.2 Office of Deputy Registrar permission letter 90

5.3 Wits post-graduate studies approval 91

5.4 Turnitin report 92

List of Tables

Section 3: **Table 1** Age groups of children receiving PSA 34

Section 3: **Table 2** Person responsible for monitoring during the procedure. 36

Section 3: **Table 3** Monitoring equipment. 37

Section 3: **Table 4** Methods of assessing the depth of sedation. 37

Section 3: **Table 5** Availability of emergency drugs. 39

Section 3: **Table 6** Availability of emergency equipment. 39

Section 3: **Table 7** Parameters assessed during the recovery period. 40

Section 3: **Table 8** Nature of sedation related complications. 41

Section 3: **Table 9** Qualification of the sedation practitioner. 42

Section 3: **Table 10** Number of drugs used in combination. 44

Section 3: **Table 11** Routes of administration. 44

Section 3: **Table 12** Person responsible for monitoring during the procedure. 45

Section 3: **Table 13** Methods of assessing the depth of sedation. 46

Section 3: **Table 14** Nature of sedation related complications. 49

Section 4: **Table 15** Project outline. 72

Section 4: **Table 16** Financial plan. 73

List of Figures

Section 3**: Figure 1** Drugs used to administer PSA. 35
Section 3: **Figure 2** Routes of administration. 36
Section 3: **Figure 3** Implementation of fasting guidelines. 38
Section 3: **Figure 4** Drugs used to administer PSA. 43
Section 3: **Figure 5** Monitoring equipment used during PSA. 45
Section 3: **Figure 6** Depth of sedation reached during PSA. 46
Section 3: **Figure 7** Availability of emergency drugs. 47
Section 3: **Figure 8** Availability of emergency equipment. 48

List of Abbreviations

AAP	American Academy of Pediatrics
AAPD	American Academy of Pediatric Dentistry
ACLS:	Advanced Cardiovascular Life Support
APLS	Advanced Paediatric Life Support
BDS	Bachelor of Dental Science
BHSc	Bachelor of Health Science
BLS	Basic Life Support
DA(SA)	Diploma in Anaesthetics of the College of Anaesthetists of South Africa
ECG	Electrocardiogram
FCA(SA)	Fellowship of the College Anaesthetists of South Africa
MBBCH	Bachelor of Medicine and Surgery
Mmed	Master of Medicine
PALS	Paediatric Advanced Life Support
PSA	Procedural Sedation and Analgesia
SADA	South African Dental Association
SAMJ	South African Medical Journal
SOSPOSA	Society of Sedation Practitioners of South Africa
SP	Sedation Practitioner
Wits	The University of the Witwatersrand

Statement

This Research Report contains a literature review, a draft article, the study proposal and appendices. The study proposal is included for background reference and not for examination. This Research Report is in the format which complies with the University of Witwatersrand's Style Guide for Theses, Dissertations and Research Reports. The draft article differs in format from the rest of the Research Report as to comply with the Author Guidelines of the South African Medical Journal.

Section 1: Literature review

1.1 Introduction

Procedural sedation and analgesia (PSA), is the administration of medication to facilitate diagnostic and therapeutic procedures, that otherwise would have to be added to overbooked theatre lists [1]. The objective of PSA is to reduce a child's fear and anxiety; provide effective pain control and prevent movement; and to decrease awareness and provide amnesia. This is achieved while maintaining the child's consciousness and cooperation [1]. PSA is performed in a safe environment, while maintaining control of the child's physiological parameters and a patent airway, thereafter returning the child to a state in which safe discharge is possible [1].

An increasing number of medical and surgical procedures being performed outside of the theatre environment, combined with the need to meet the ethical and social imperatives to dimmish pain, alleviate anxiety and optimize patient comfort during a procedure, has led to the world-wide practice of PSA [2]. Different publications have recorded a low incidence of serious adverse events and a relatively low risk to PSA, yet continue to define the assessment, management and rescue of the paediatric airway as a crucial competency of the sedation practitioner (SP) [3,1]. The greatest risk is respiratory depression, which if not recognized and properly treated, can lead to hypoxia and possibly death or permanent neurological injury [4].

International sedation guidelines support sedation training, as a lack of formal training has been found to contribute to sedation related adverse events [5]. The South African Society of Anaestheisologists (SASA) guidelines for paediatric PSA for 2021, categorize adverse events as follows [1]:

- Lesser adverse events (a short period of oxygen desaturation).
- Standard or moderate adverse events (lowest oxygen saturation at 75% or lasting longer than 60 seconds).
- Critical adverse events (permanent neurological injury, admission to hospital, CPR and tracheal intubation or death).

In 2016 the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) PSA guidelines, highlighted factors that contribute to the safe administration of PSA and the incidence of adverse events. They include the following [6]:

- Careful pre-sedation evaluation of medical or surgical conditions.
- Appropriate fasting for elective procedures and a discerning depth of sedation for non-starved emergencies.
- Focused airway examination for anatomical causes of potential obstruction.

- A clear understanding of the medications pharmacokinetic and pharmacodynamic effects and drug interactions.
- Appropriate training and skill to identify and rescue a compromised airway.
- Age and size appropriate equipment for airway management and venous access.
- Appropriate medications and reversal agents.
- Sufficient staff to carry out the procedure and monitor the patient.
- Appropriate physiological monitoring during and after the procedure.
- Properly equipped and staffed recovery area.
- Recovery to the pre-sedation level of consciousness before discharge.
- Appropriate discharge instructions.

SASA paediatric PSA guidelines for 2021 support the same factors and would add inappropriate patient selection and procedure suitability for sedation as contributors to adverse events [1].

International guidelines have focused on these factors to promote the safe practice of paediatric PSA. In 2021, Finland, a country without paediatric PSA guidelines, launched a national survey revealing variable practices in paediatric PSA and patient monitoring [7]. The survey found that only one third of sedation practitioners had undergone formal training. Only 39% of units practicing paediatric PSA recorded data on sedation related adverse events. There was no objective measurement of sedation depth and whilst 78% of sedation practitioners used pulse oximetry, only 39% used non-invasive blood pressure monitoring (NIBP) and 28% used electrocardiogram (ECG) recordings. The survey revealed that 98% of sedation practitioners had supplemental oxygen available and 92% had appropriate ventilation equipment [7].

In the Netherlands, two sedation related paediatric fatalities led to the 2009 nationwide investigation into the adherence of general paediatricians to safety standards and PSA guidelines [8]. Four areas of patient sedation were assessed, namely: pre-sedation assessment, monitoring during procedural sedation, recovery after procedural sedation and facilities and competencies for emergency and rescue. These were each scored 0-10. A score of more than 8 represented satisfactory adherence whilst a score of less than 6 represented unacceptably low adherence to guidelines. Only a minority achieved a satisfactory adherence status (>8), full adherence was rare. Large numbers of respondents scored below six. The survey concluded that potentially unsafe PSA practices are common under Dutch general paediatricians, despite availability of guidelines [8].

In 2015, SAMJ published a study titled “Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa”, which found alarming, self-reported figures of guideline non-adherence [9]. The study found that 44% of Gauteng based dentists practised paediatric PSA. The majority of patients sedated were between one and five years old. Whilst most sedation practitioners in these dental rooms

intended to achieve mild to moderate sedation, some administered deep sedation and even general anaesthesia. The findings included the following figures [9]:

- 83% of sedation practitioners (SP's) documented pre-sedation assessment and 75.6% documented informed consent.
- 28.1% of SP's used a combination of three or more agents.
- 41.3% of SP's did not use any monitoring equipment.
- 41.3% of SP's were responsible for the dental procedure as well as the sedation.
- 43.2% of SP's did not keep any recommended emergency drugs.
- 19.6% of SP's did not have any emergency resuscitation equipment available.
- 78% of SP's had supplemental oxygen, (71% had facemask oxygen).
- 47.8 % of SP's had access to Bag-mask-ventilation
- 34.8% of SP's had access to oropharyngeal and nasopharyngeal airways.
- 30.4% of SP's had access to IV cannulas for IV access.
- 30.4% of SP's had access to laryngoscopy sets.
- 17.4% of SP's had access to defibrillators.

Following this publication, SASA released the updated paediatric PSA guidelines for 2016. The Wits Department of Anaesthesiology: Dental portfolio and the Wits Dental Science school intervened by placing emphasis on "safe sedation principles", in the form of lectures during the dental student's sedation module. The SASA paediatric PSA guidelines were introduced to the dental students with the intention that greater awareness of the guidelines may result in improved guideline adherence. To date there has been no follow up study to measure the effect of this intervention.

Literature confirms the need for sedation training and has recommendations about what it should contain. In the Emergency Department setting, the study "Development and implementation of an education and credentialing program to provide safe paediatric procedural sedation" concluded that training programs were "found useful" by sedation practitioners and that such programs should include the following [10]:

- Sedation manual.
- Lectures.
- Treatment order forms and checklists.
- Parent consent and counselling skills.

In 2009, a report from the Pediatric Sedation Research Consortium, published in Pediatric Anaesthesiology, documented the incidence and nature of sedation related adverse events during procedural sedation outside of the operating room [11]. After confirming that it is unlikely to have "serious adverse events", the study found that safety depends on a sedation practitioners' ability to handle "less serious adverse

events". They recommend, therefore, that training sedation practitioners should focus on the management of "more common" adverse events, including the following:

- Desaturation below 90% for more than thirty seconds.
- Central apnoea and airway obstruction.
- Laryngospasm.
- Excessive secretions.
- Vomiting.

The national survey of paediatrician's adherence to PSA safety standards in the Netherlands, which found potentially unsafe PSA practices to be common, recommended that guidelines should include a goal directed plan for continuous quality assurance and improvement, and repeated measurements of adherence to guidelines.

This recommendation is repeated in the SASA Paediatric PSA guidelines for 2021, which stipulate that in accordance with good clinical governance [1]:

- All Sedation Practitioners (SP's) are required to be registered as Medical Practitioners by the Health Professions Council of South Africa (HPCSA) and comply with current safety regulations of the HPCSA.
- SP's should have clinical accountability that includes evaluation of expertise, clinical appraisal and implementation of SASA guidelines on PSA for children. This includes keeping a logbook of cases performed under sedation and documentation of adverse incidents and accidents.
- SP's should have in-house training sessions for the sedation team.

It is also recommended that:

- Facilities undergo inspection to comply with quality assurance policies and procedures.
- SP's must have an appraisal which is overseen by the Society of Sedation Practitioners of South Africa (SOSPOSA) every two years. Where after they will receive a certificate of good standing.
- All sedation staff should keep a record of Basic Life Support (BLS) certification.
- SP's should keep record of Pediatric Advanced Life Support (PALS) and Advanced Cardiac Life Support (ACLS) certification.

Since the publication of "Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa", there has not been a follow up study amongst sedation practitioners in the dental rooms of Wits Dental Science school graduates.

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operating room: a report from the Pediatric Sedation Research Consortium. *Anesthesia and analgesia*. 2009; 108(3): 795–804.

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Research

Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text.

Structured abstract

- This should be 250-400 words, with the following recommended headings:

o **Background:** why the study is being done and how it relates to other published work.

o **Objectives:** what the study intends to find out

o **Methods:** must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.

o **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.

o **Conclusion:** must be supported by the data, include recommendations for further study/actions.

- Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.
- Do not include any references in the abstracts.

Here is an example of a good abstract.

Main article

All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

The following are additional heading or section options that may appear within these:

- Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.
- Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.
- Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc)that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.
- Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.
- Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any.

Results

- Start with description of the population and sample. Include key characteristics of comparison groups.
- Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.
- Do not replicate data in tables and in text.
- If presenting mean and standard deviations, specify this clearly. Our house style is to present this as follows:
- E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the ± symbol for mean (SD).
- Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

Discussion

Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

- Statement of principal findings

- Strengths and weaknesses of the study
- Contribution to the body of knowledge
- Strengths and weaknesses in relation to other studies
- The meaning of the study – e.g. what this study means to clinicians and policymakers
- Unanswered questions and recommendations for future research

Conclusions

This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

References

NB: *Only complete, correctly formatted reference lists in Vancouver style will be accepted. Reference lists must be generated manually and not with the use of reference manager software. Endnotes must* ***not*** *be used.*

- Authors must verify references from original sources.
- Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6]
- All references should be listed at the end of the article in numerical order of appearance in the Vancouver style (not alphabetical order).
- Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus.
- Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al.
- Volume and issue numbers should be given.
- First and last page, in full, should be given e.g.: 1215-1217 **not** 1215-17.
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Some examples:

- *Journal references:* Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. http://dx.doi.org/10.1000/hgjr.182
- *Book references:* Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101.

- *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.
- *Internet references:* World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: WHO, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).
- Legal references

• Government Gazettes:

National Department of Health, South Africa. National Policy for Health Act, 1990 (Act No. 116 of 1990). Free primary health care services. Government Gazette No. 17507:1514. 1996.

In this example, 17507 is the Gazette Number. This is followed by :1514 - this is the notice number in this Gazette.

• Provincial Gazettes:

Gauteng Province, South Africa; Department of Agriculture, Conservation, Environment and Land Affairs. Publication of the Gauteng health care waste management draft regulations. Gauteng Provincial Gazette No. 373:3003, 2003.

• Acts:

South Africa. National Health Act No. 61 of 2003.

• Regulations to an Act:

South Africa. National Health Act of 2003. Regulations: Rendering of clinical forensic medicine services. Government Gazette No. 35099, 2012. (Published under Government Notice R176).

• Bills:

South Africa. Traditional Health Practitioners Bill, No. B66B-2003, 2006.

• Green/white papers:

South Africa. Department of Health Green Paper: National Health Insurance in South Africa. 2011.

• Case law:

Rex v Jopp and Another 1949 (4) SA 11 (N)

Rex v Jopp and Another: Name of the parties concerned

1949: Date of decision (or when the case was heard)

(4): Volume number

SA: SA Law Reports

11: Page or section number

(N): In this case Natal - where the case was heard. Similarly, (C) woud indicate Cape, (G) Gauteng, and so on.

NOTE: no . after the v

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- Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'.

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From submission to acceptance

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o Manuscript

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3. If the CE has an author queries, he/she will contact the corresponding author and send them the copyedited Word doc, asking them to solve the queries by means of track changes or comment boxes.

4. <u>The authors are typically asked to respond within 1-3 days.</u> Any comments/changes must be clearly indicated e.g. by means of track changes. Do not work in the original manuscript - work in the copyedited file sent to you and make your changes clear.

5. The CE will finalise the article and then it will be typeset.

6. Once typeset, the CE will send a PDF of the file to the authors to complete their final check, while simultaneously sending to the 2nd-eye proofreader.

7. <u>The authors are typically asked to complete their final check and sign-off within 1-2 days.</u> No major additional changes can be accommodated at this point.

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Section 3: Draft Article

Paediatric dental chair procedural sedation and analgesia: A follow up study.

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Abstract

Background

The South African Society of Anaesthesiologists (SASA) paediatric procedural sedation and analgesia (PSA) guidelines provide instructions for the safe administration of paediatric PSA and the management of complications. The pilot study found a lack of adherence to the recommended safety standards among dentists in Gauteng. The departments of Anaesthesiology and Dental Science at Wits placed emphasis on "safe sedation principles" with the intention that greater awareness of the guidelines may result in improved guideline adherence.

Aim

The aim of this study is to determine if there has been a change in paediatric dental chair PSA practice and guideline adherence among Wits BDS graduates, since the publication of "Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa" in 2015.

Methods

A prospective, contextual, descriptive survey study design was used. The survey was adapted from the pilot study to define the current practice of paediatric dental chair PSA among Wits BDS graduates and determine the level of guideline adherence. The findings of the pilot and follow up studies were compared.

Results

The study found that 62% of dentists had no sedation training. Sixty-six percent of sedation practitioners working for dentists were sedation trained medical practitioners or anaesthetists. Twenty-two percent of dentists continue to perform the role of operator and sedation practitioner simultaneously.

There remains a lack of paediatric PSA guideline adherence despite improvements in the following areas: documentation of written informed consent; implementation of fasting guidelines; use of monitoring equipment, use of staffed recovery areas and availability of emergency drugs and equipment.

The proportion of procedures performed under deep sedation and general anaesthesia increased as did the number of sedation related complications. The most common complications were oxygen desaturation (62%), airway obstruction (38%) and apnoea (19%). No cardiac arrest or deaths were reported.

Conclusion

The follow up study found a lack of paediatric PSA guideline awareness and unsafe practice of paediatric dental chair PSA among Wits BDS graduates from 2016 to 2021. The study has highlighted a need for postgraduate accredited sedation training and the ongoing audit of paediatric dental chair PSA.

Introduction

Procedural sedation and analgesia (PSA), is the administration of medication to facilitate diagnostic and therapeutic procedures, that would otherwise have to be performed in theatre. The objectives of PSA are to reduce a child's fear and anxiety; provide effective pain control and limit movement; and to decrease awareness and provide amnesia. This is achieved while maintaining the child's consciousness and co-operation. PSA should be performed in a safe environment, while ensuring that the child's physiological parameters and airway are safely maintained, until discharged. [1]

International sedation guidelines support sedation training, as a lack of formal training has been found to contribute to sedation related adverse events [2]. The South African Society of Anaesthesiologists (SASA) guidelines for paediatric PSA for 2021, categorize adverse events as Lesser adverse events (a short period of oxygen desaturation); Standard or Moderate adverse events (lowest oxygen saturation at 75% or lasting longer than 60 seconds) and Critical adverse events (permanent neurological injury, admission to hospital, CPR and tracheal intubation or death). The guidelines identify factors that contribute to adverse events, such as the intravenous administration of a combination of drugs, the availability of capnography for the monitoring of ventilation and the ASA classification of children sedated. They also provide information regarding drugs which can be used for safe PSA administration. Furthermore, there are recommendations for the ongoing assessment of sedation practitioners (SP's) professional registration, logbooks and clinical implementation of the guidelines every two years, which should be overseen by the Society of Sedation Practitioners of South Africa (SOSPOSA), as well as record of BLS, ACLS and PALS training. [1]

In 2015, SAMJ published the pilot study titled "Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa". The study found alarming, self-reported figures of guideline non-adherence regarding patient consent, record keeping, depth of sedation administered, intraoperative and postoperative patient monitoring and the availability of emergency drugs and equipment [3]. Following this publication, the Wits departments of Anaesthesiology and Dental sciences intervened by placing emphasis on safe sedation principles in the form of lectures provided to Wits BDS students. This follow up study aims to describe the paediatric PSA practice of Wits BDS graduates between 2016 – 2021 and compare the results to the original study.

Methods

A literature review was conducted to identify factors that lead to adverse events in paediatric patients undergoing dental procedures and PSA. The 2021 SASA paediatric PSA guidelines served as the reference for standard of care [1].

The study was designed in accordance with the principles of the Declaration of Helsinki [4] and the South African Guidelines of Good Clinical practice [5]. A prospective, contextual, descriptive survey study design was used to create a follow up study of the pilot study published in the SAMJ in 2015, "Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa".

Written permission to replicate questions from the pilot study was granted by Dr F Bham, co-author of this follow up study. The survey intentionally replicated questions from the pilot

study to ensure reliability and allow for valid comparison. A web-based data collection sheet was designed using SurveyMonkey [6].

A convenience sampling method was used. All Wits BDS graduates between 2016 and 2021 were included in the study regardless of their location of practice at the time of data collection. The sample size of 112 graduates, a population proportion of 50% and a confidence interval (CI) of 95% was used to determine a minimal response rate of 86 graduates.

An information sheet was designed, which explained that participation was voluntary and that anonymity and confidentiality were ensured. Graduates were informed that completion of the online survey implied consent.

Ethics approval was granted by the Wits Human Research Ethics Committee (Medical) (Reference R14/49) and permission granted by the Wits Office of Deputy Registrar.

Due to the Protection of Personal Information Act 4(POPIA) of 2013 [7], the Deputy Registrar Office was restricted to supplying the publicly available names of graduates in the form of annual graduation booklets. The Deputy Registrar Office and Wits Alumni Office distributed the survey electronically via student emails on the author's behalf. Additionally, social media platforms and publicized dental practice advertisements were used to compile a list of contact information for the study population. The graduates were contacted individually via phone and/or email. Consenting participants were asked if they practiced paediatric PSA, those who answered 'No,' had their response documented and took no further part in the study. Those who answered 'Yes,' were invited to complete the survey which was made available as an electronic link via email or WhatsApp.

The responses were recorded anonymously on SurveyMonkey [6], where data is kept secure on a virtual database with electronic security passcodes. Data was collected from December 2022 until March 2023.

A biostatistician was employed to analyse data. Data was analysed using R v4.2.2 (R Core Team, 2022) [8]. All data from the 2023 study was categorical, and the results expressed as counts (percentage, %). All results were descriptive, except where comparisons between the pilot study and the follow up study were made. These comparisons were only made when the choices available in a survey question were mutually exclusive (only one option could be chosen). In all such cases, a Fisher's Exact Test was used to draw statistical inference, with a statistical significance threshold of $p < 0.05$. For all questions, the data was reported in tabulated and plotted formats.

Results

Of the 112 Wits BDS graduates between 2016 and 2021, 101 consented to partake in the follow up study. Of the 101 participants, 32 indicated that they do not treat the paediatric population and therefore were not required to complete the survey. The remaining 69 participants all started the survey, however, not all questions were answered by all participants, and it appears that one participant abandoned the questionnaire before completing it. As every question was not answered by all respondents, the sample size for each question is given in the caption of the table and the legend of the figure that accompany each question. In questions where choices were not mutually exclusive (i.e., more than one option could be selected), counts are for the number selecting a particular item and therefore total counts for a question will add to more than the sample size.

Percentages for these tables reflect the percentage of the sample that selected an item, and therefore will also add to more than 100%.

The demographics of the Wits BDS graduates were determined before asking participants what level of sedation training they had acquired. Then participants were asked who, in their dental rooms, was responsible for administering PSA and what level of training that professional had acquired.

Demographics of Wits BDS graduates.

The Median age was 29 years, with a minimum age of 24 years, and a maximum age of 40 years. Seventy-one percent (N = 48) of the participants were female.

Wits BDS graduates' level of sedation training.

Thirty-eight percent (N = 26) of dentists performing paediatric PSA had accredited sedation training. BLS certification was held by 91% (N = 62) of dentists, however only 27% (N = 18) had attended an APLS/PALS course and only 24% (N = 16) of dentists were members of SOSPOSA.

Qualification of the sedation practitioner.

The dental procedure and PSA were performed by 22% (N = 15) of dentists. Medical practitioners with sedation training (N = 22) or anaesthetists (N = 24) administered the PSA in 66% of Wits BDS graduates dental rooms.

To describe the current practice of paediatric PSA, participants were questioned about the number and age of patients sedated in their dental rooms, patient monitoring, the drugs used and the depth of sedation reached.

Frequency of PSA procedures performed.

PSA was infrequently performed in the dental rooms of most Wits BDS graduates, 68% (N = 45) reporting 1-5 PSA procedures per month and 20% (N = 13) reporting 6-15 PSA procedures per month. However, the range was extremely right skewed, with 8% (N = 5) of respondents undertaking 31 or more sedations per month.

Age groups of children receiving PSA.

Table 1. Age groups of children receiving PSA.

(N = 65; categories were not mutually exclusive)

Category	N (%)
< 1 year	1 (2%)
1-5 years	56 (86%)
6-8 years	49 (75%)
9-12 years	22 (34%)

Drugs used to administer PSA.

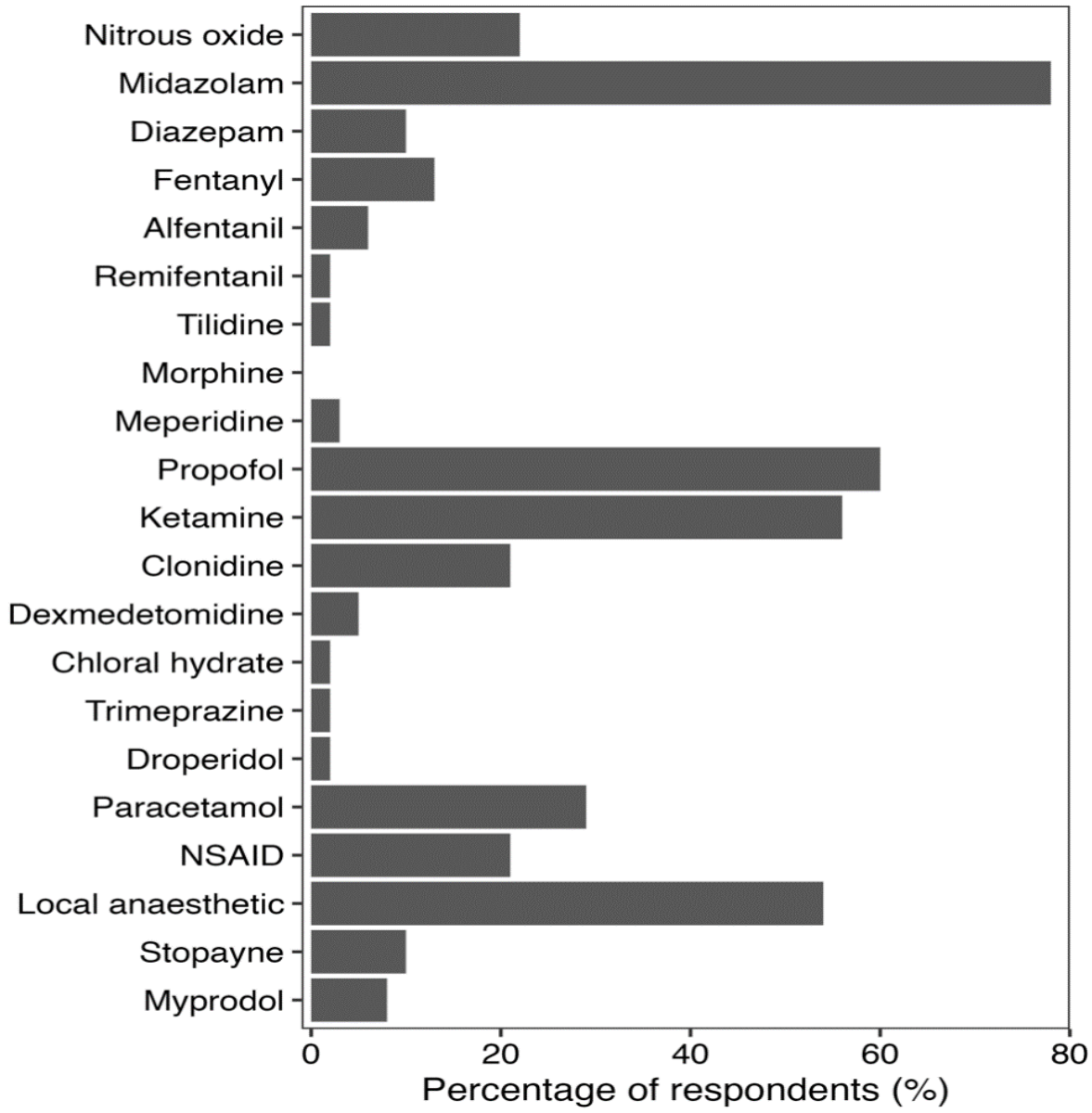

Figure 1. Drugs used to administer PSA (N = 63)

Number of drugs used in combination.

Seventy-two percent (N = 44) of SPs used a combination of two or more drugs and only 20% (N = 12) administered simple sedation with a single drug.

Routes of administration.

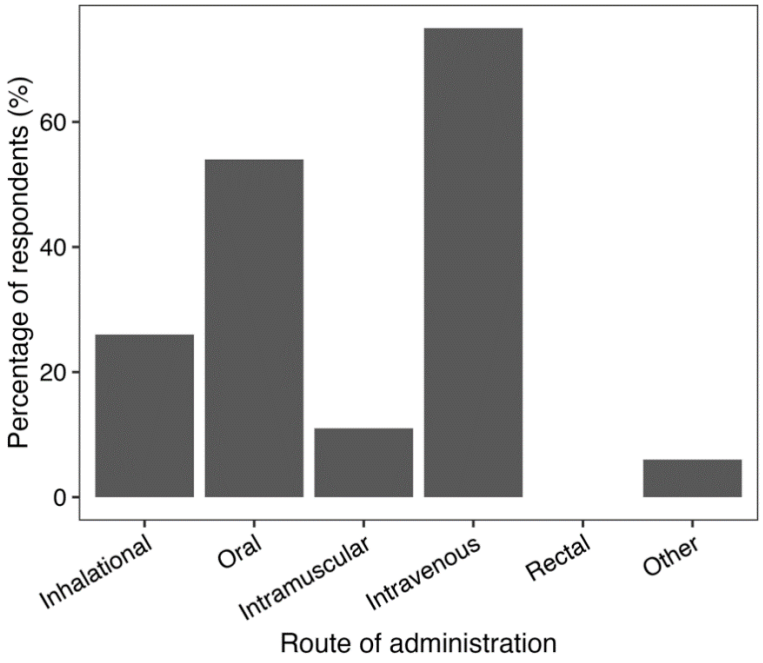

Figure 2. Routes of administration (N = 65; categories were not mutually exclusive)

Person responsible for patient monitoring during the procedure.

Table 2. Person responsible for monitoring (N = 65)

Responsible person	N (%)
Dentist	18 (28%)
Nurse	1 (2%)
Medical practitioner	1 (2%)
Medical practitioner with sedation training	20 (31%)
Anaesthetist	22 (34%)
Other	3 (5%)

Monitoring equipment.

Table 3. Monitoring equipment

(N = 65; categories were not mutually exclusive)

Category	N (%)
Pulse oximetry	56 (86%)
Non-invasive blood pressure	35 (54%)
Capnography	21 (32%)
Precordial stethoscope	12 (18%)
ECG	26 (40%)
Thermometer	6 (9%)
Sedation monitoring chart	30 (46%)
None	5 (8%)

Methods of assessing the depth of sedation.

Table 4. Assessment of depth of sedation

(N = 59; categories were not mutually exclusive)

Method of monitoring	N (%)
Bispectral index monitoring	6 (10%)
Sedation scale	22 (37%)
Response to commands/touch/pain at regular intervals	36 (61%)
Response to commands/touch/pain only when over-sedation is suspected	12 (20%)
None	10 (17%)

Depths of sedation.

Wits BDS graduates were asked which depth of sedation had been reached during the administration of paediatric PSA in their rooms. Fifty-five percent (N = 36) of dentists had performed or witnessed moderate sedation, 45% (N = 29) deep sedation and 15% (N = 10) had performed or witnessed general anaesthesia. Thirty-four percent (N = 22) performed minimal sedation only.

To determine adherence to the 2021 SASA paediatric PSA guidelines, Wits BDS graduates were questioned about the health status of patients receiving PSA, recording of pre-sedation assessments and written consent, implementation of fasting guidelines, the assessment parameters and personnel responsible for patient recovery as well as availability of recommended emergency drugs and equipment.

Health status of children sedated.

Ninety-eight percent (N = 64) of dentists performed procedural sedation on healthy children, 49% (N = 32) of dentists also undertook procedural sedation on children with mild systemic disease and 8% (N = 5) of dentists' sedate children with severe systemic disease.

Documentation of pre-sedation assessment and written informed consent.

Eighty-three percent (N = 54) of respondents document a pre-sedation assessment and 95% (N = 62) document written informed consent.

Implementation of fasting guidelines.

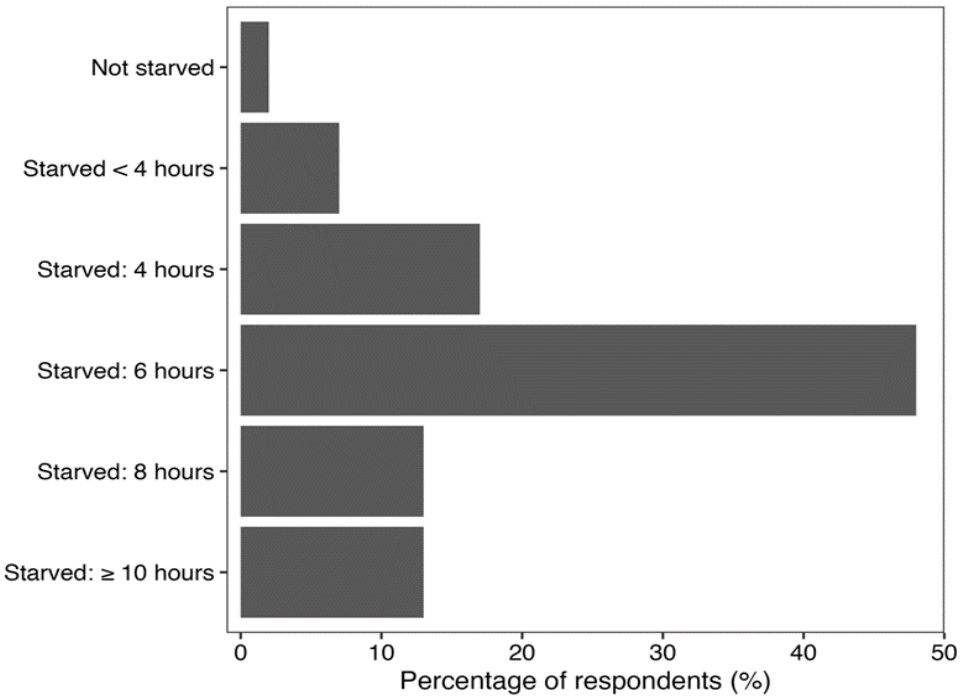

Figure 3. Time between last meal and sedation (n = 60)

Availability of emergency drugs.

Table 5. Emergency drugs.
(N = 64; categories were not mutually exclusive)

Drugs	N (%)
Adrenaline	48 (75%)
Atropine	32 (50%)
Flumazenil	18 (28%)
Naloxone	21 (33%)
Succinylcholine	19 (30%)
None of the drugs listed above	15 (23%)

Availability of emergency equipment.

Table 6. Available equipment
(N = 64; categories were not mutually exclusive)

Equipment	N (%)
Face mask	51 (80%)
Laryngoscope set	25 (39%)
Endotracheal tubes	24 (38%)
Oropharyngeal/nasopharyngeal airways	29 (45%)
End-tidal carbon dioxide monitoring	13 (20%)
Oxygen supply	46 (72%)
Bag-value ventilation device	38 (59%)
Defibrillator	31 (48%)
Intravenous cannula	26 (41%)
Intravenous fluids	31 (48%)
Blood glucose testing device	32 (50%)
None of the listed items	5 (8%)

Use of staffed recovery area.

Eighty-five percent (N = 55) of dentists have a staffed recovery area, while 11% (N = 7) report having another arrangement for postoperative monitoring. Five percent (N = 3) reported having no recovery area at all.

Parameters assessed during the recovery period.

Table 7. Parameters assessed during recovery.

(N = 65; categories were not mutually exclusive)

Category	N (%)
Level of consciousness	61 (94%)
Respiration	39 (60%)
Oxygen saturation	40 (62%)
Movement	43 (66%)
Temperature	12 (18%)
Pain	29 (45%)
Bleeding	37 (57%)
Ability to drink	18 (28%)
Nausea/vomiting	31 (48%)
Availability of a caregiver	46 (71%)
None of the listed options	2 (3%)

Participants were asked if they had experienced sedation related complications in their dental rooms and to specify the nature of sedation related complications.

Sedation related complications.

Twenty-six percent (N = 17) of dentists reported having experienced complications associated with PSA.

Table 8. Nature of sedation related complications

(N = 21; categories were not mutually exclusive)

Complication	N (%)
Airway obstruction	8 (38%)
Apnoea	4 (19%)
Oxygen desaturation	13 (62%)
Vomiting	9 (43%)
Aspiration	2 (10%)
Hypotension	1 (5%)
Anaphylaxis	1 (5%)
Other allergic reaction	2 (10%)
Cardiac arrest	0 (0%)
Death	0 (0%)
Other	2 (10%)

Awareness of SASA guidelines, the pilot study and interest in further training.

Thirty-four percent (N = 23) of Wits BDS graduates were aware of the SASA paediatric PSA guidelines. One participant used an alternative guideline namely, the Intercollegiate Advisory Committee for Sedation in Dentistry (IACDS). Nineteen percent (N = 13) were familiar with the pilot study, titled "Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa", which was published in SAMJ in 2015.

Ninety-one percent (N = 62) of Wits BDS graduates indicated that they desire further CPD accredited sedation training.

Comparison of results

The results of the initial study conducted in 2013, "Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa" and the results of this follow up study, were compared to determine if there has been a change in paediatric PSA practice and guideline adherence.

Demographics.

The age group of respondents in the follow up study was lower and were less spread. Whereas the median age was 29 in the follow up study, it was 43 in the pilot study. While both years had the same minimum age (24 years), the maximum age was different, 40 years old in follow up study and 74 years old in the pilot study. Females constituted 34% (N = 15) of the pilot study but significantly, 71% (N = 48) of the follow up study.

Comparison of dental practitioners' level of training.

Almost all dentists had attended BLS training in both studies. APLS/PALS course attendance was low in both the pilot (15%) and the follow up study (27%). The number of SOSPOSA registered members increased from 5% to 24%, although this change was not statistically significant.

There was a statistically insignificant decrease (p=0.146) in the proportion of respondents having acquired accredited PSA training, from 57% (N = 13) in the pilot study to 38% (N = 26) in the follow up study.

Qualification of the sedation practitioner.

The follow up study found that fewer dentists are performing procedures and PSA simultaneously and that more anaesthetists are responsible for the dental chair PSA.

Table 9. Qualification of the sedation practitioner.

	Year*	
Category	2013	2023
Dentist	22 (46%)	15 (22%)
Nurse	0 (0%)	0 (0%)
Medical practitioner	1 (2%)	2 (3%)
Medical practitioner with sedation training	15 (31%)	22 (32%)
Anaesthetist	10 (21%)	24 (35%)
Other	0 (0%)	5 (7%)

*Fisher's Exact test: p = 0.023; N (2013) = 48; N (2023) = 68

Frequency of PSA procedures performed.

In both studies, the number of dental procedures that required paediatric dental chair PSA was five, or fewer, per month in approximately 70% of respondents' dental rooms. Similarly, the range was extremely right skewed, with 8% of respondents undertaking 31 or more sedations per month in both studies.

Age groups of children receiving PSA.

In both studies 75% of respondents indicated that they perform PSA on children in the 1–8 year-old age group and only 4% perform PSA on children under the age of 1 year.

Drugs used to administer PSA.

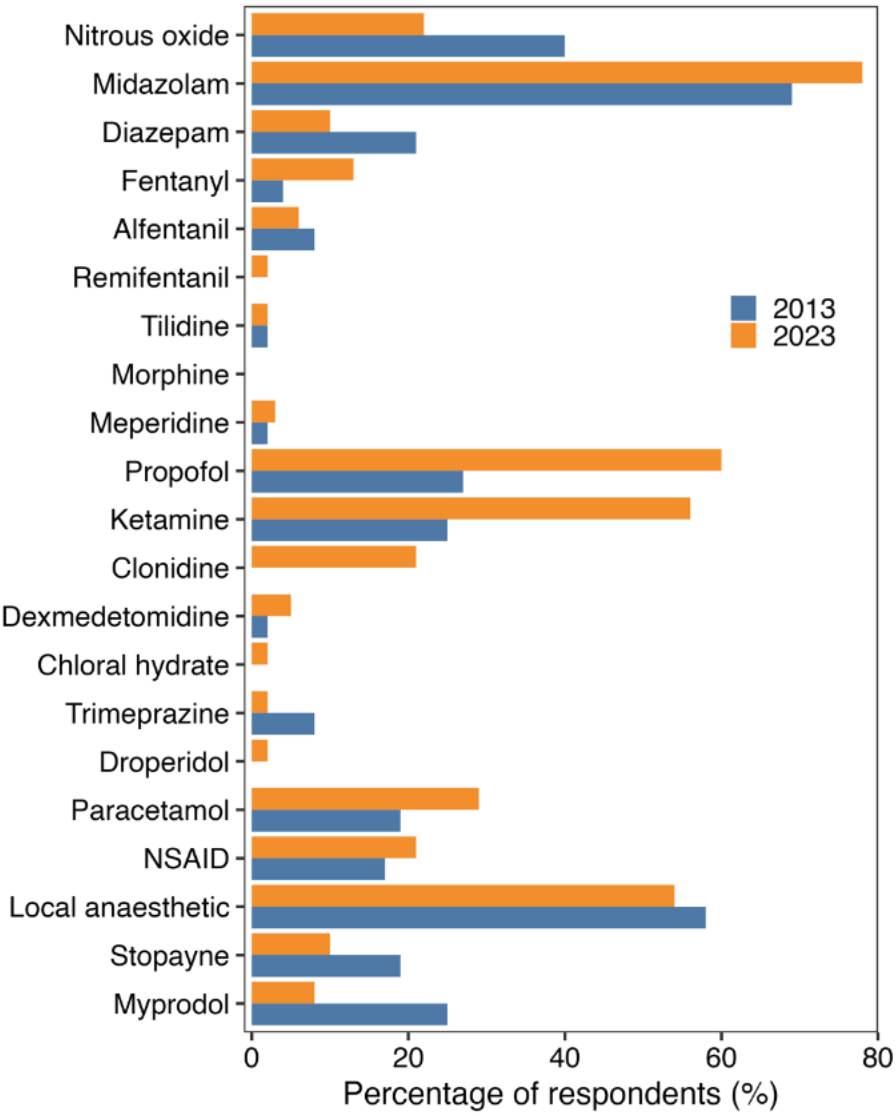

Figure 4. Drugs used for PSA [N (2013) = 48, N (2023) = 63].

Number of drugs used in combination.

Table 10. Number of drugs used in combination.
(Excluding paracetamol, NSAIDs, and local anaesthetics)

	Year*	
Number of drugs	2013	2023
1	10 (26%)	12 (20%)
2	13 (34%)	24 (39%)
3	8 (21%)	15 (25%)
4+	1 (3%)	5 (8%)
Do not know	6 (16%)	5 (8%)

*Fisher's Exact test: p = 0.559; N (2013) = 38, N (2023) = 61

Routes of administration.

Table 11. Routes of administration (Categories were not mutually exclusive)

	Year	
Route	2013	2023
Inhalation	20 (42%)	17 (26%)
Oral	25 (52%)	35 (54%)
Intramuscular	1 (2%)	7 (11%)
Intravenous	22 (46%)	49 (75%)
Rectal	0 (0%)	0 (0%)
Other	0 (0%)	4 (6%)

N (2013) = 48; N (2023) = 65

Person responsible for monitoring during the procedure.

Table 12. Person responsible for monitoring during the procedure

	Year*	
Monitoring	2013	2023
Dentist	19 (41%)	18 (28%)
Nurse	1 (2%)	1 (2%)
Medical Practitioner	0 (0%)	1 (2%)
Medical practitioner with sedation training	16 (35%)	20 (31%)
Anaesthetist	9 (20%)	22 (34%)
Other	1 (2%)	3 (5%)

*Fisher's Exact test: p = 0.403; N (2013) = 46; N (2023) = 65

Monitoring equipment used during PSA.

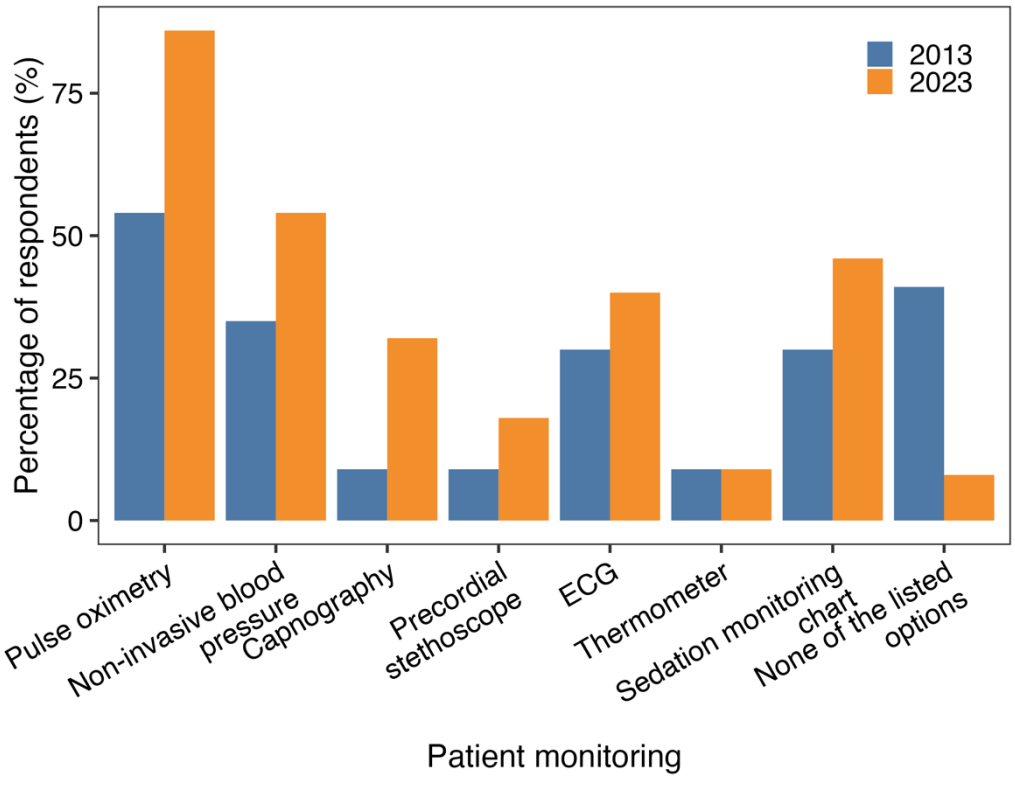

Figure 5. Monitoring equipment used during PSA (categories were not mutually exclusive) [N (2013) = 46; N (2023) = 65].

Methods of assessing depth of sedation.

Table 13. Assessment of depth of sedation

(Categories were not mutually exclusive)

	Year	
Assessment method	2013	2023
Bispectral index monitoring	7 (16%)	6 (10%)
Sedation scale	10 (22%)	22 (37%)
Response to commands/touch/pain at regular intervals	30 (67%)	36 (61%)
Response to commands/touch/pain only when over-sedation is suspected	3 (7%)	12 (20%)
None	13 (29%)	10 (17%)

N (2013) = 45; N (2023) = 59

Depth of sedation reached during PSA administration.

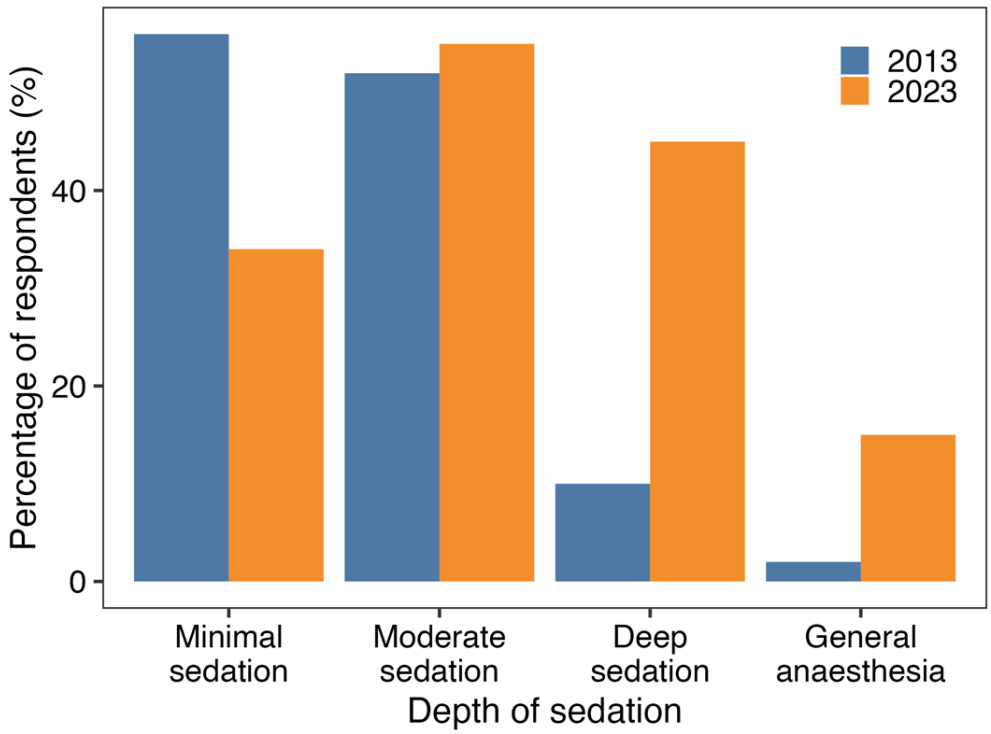

Figure 6. Depth of sedation (categories were not mutually exclusive). [N (2015) = 48; N (2023) = 66].

Health status of children receiving PSA.

In both studies respondents performed PSA in healthy children and children with mild systemic disease. In 2013, 4% (N = 2) of dentists performed PSA on children with severe systemic disease. In 2023, 8% (N = 5) of Wits BDS graduates performed PSA on children with severe systemic disease.

Documentation of pre-sedation assessment and written informed consent.

There was no change in the number of documented pre-sedation assessments. In both studies 17% of respondents indicated that they do not document any pre-sedation assessment.

There was a statistically significant increase (p=0.003) in the number of respondents who document written informed consent, from 76% (N = 34) in the pilot study to 95% (N = 62) in the follow up study.

Implementation of fasting guidelines.

In the pilot study 27% of respondents indicated that children were not starved for procedures performed with PSA. In the follow up study one respondent indicated that they did not starve their patients for procedures with PSA. The number of respondents who starve their patients for 6 hours following a meal for procedures performed with PSA (in accordance with SASA PSA guidelines) has increased significantly from 24% to 48% ($p < 0.001$). There is a trend away from insufficient starvation times under 6 hours (63% to 26%) and towards excessive starvation times of 8 to 10 hours (13% to 26%).

Availability of emergency drugs.

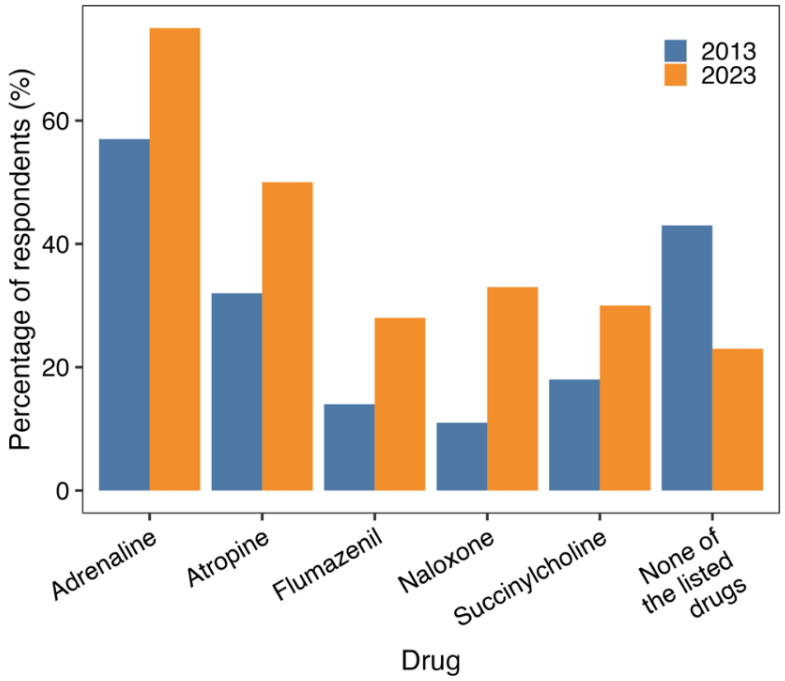

Figure 7. Emergency drugs available to sedation practitioners (categories were not mutually exclusive) [N (2013) = 44; N (2023) = 64].

Availability of emergency equipment.

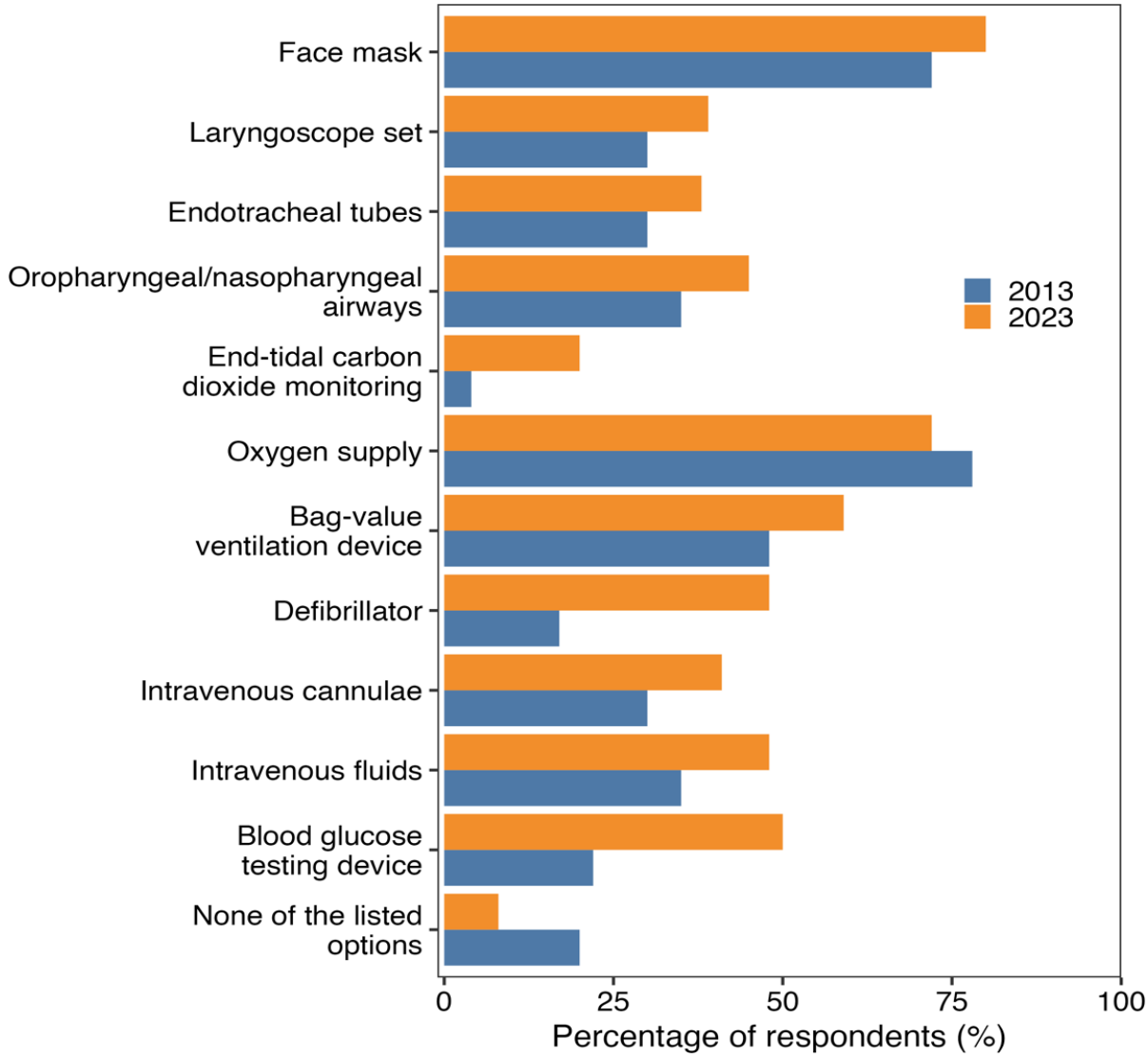

Figure 8. Emergency equipment available to sedation practitioners (categories were not mutually exclusive) [N (2013) = 46; N (2023) = 64].

Use of staffed recovery areas.

There was a statistically significant increase in the use of staffed recovery areas between the pilot and follow up studies from 58% (N = 26) to 85% (N = 55). The number of respondents who indicated that they do not utilise any form of post operative monitoring has decreased from 38% (N = 17) to 5% (N = 3)

Parameters assessed during recovery.

In both the pilot and follow up studies, the patient's level of consciousness was assessed by 94% of respondents. Monitoring of oxygen saturation in the recovery period has increased from 39% (N = 17) to 62% (N = 40). In both studies less than 65% of respondents routinely monitor respiratory effort and oxygen saturation, pain, bleeding, nausea and vomiting.

Sedation related complications.

There was a statistically significant increase ($p<0.001$) in the number of respondents who indicated that they had experienced a complication related to PSA, from 2% (N = 1) in the pilot study to 26% (N = 17) in the follow up study.

Table 14. Nature of sedation related complications

(Categories were not mutually exclusive)

	Year*	
Complication	2013	2023
Airway obstruction	0 (0%)	8 (38%)
Apnoea	0 (0%)	4 (19%)
Oxygen desaturation	0 (0%)	13 (62%)
Vomiting	0 (0%)	9 (43%)
Aspiration	0 (0%)	2 (10%)
Hypotension	0 (0%)	1 (5%)
Anaphylaxis	0 (0%)	1 (5%)
Other allergic reaction	1 (100%)	2 (10%)
Cardiac arrest	0 (0%)	0 (0%)
Death	0 (0%)	0 (0%)
Other	0 (0%)	2 (10%)

N (2013) = 1; N (2023) = 21

Awareness of SASA PSA guidelines.

There was no improvement in the awareness of the SASA paediatric PSA guidelines between the pilot study, 32% (N = 12) and follow up study, 34% (N = 23).

Dentists interested in attending further sedation training.

The change in the number of respondents indicating that they would be interested in attending CPD accredited sedation training was statistically insignificant, increasing from 82% in the pilot study to 91% in the follow up study.

Discussion

A pilot study titled, “Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa”, was published in the SAMJ in 2015 and concluded that there was a concerning lack of adherence to recommended safety standards [3]. Subsequent interventions were

implemented at Wits university in an attempt to improve SASA paediatric PSA guideline awareness among Wits BDS students. In this follow up study, we investigated whether there has been a change in paediatric dental chair PSA practice and guideline adherence among Wits BDS graduates, after the publication of "Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa".

The follow up study found improvements in paediatric PSA practice and guideline adherence, despite there being no increase in awareness of SASA paediatric PSA guidelines. The implication of this finding is that Wits BDS graduates retained some of the safe sedation principles they were taught as undergraduates, without recollection of the title of the guidelines. Furthermore, a greater proportion of dentists have involved anaesthetists and medical practitioners with sedation training, inadvertently implementing safe sedation principles. Although guideline adherence has increased in the follow up group, adherence to recommended safety standards by Wits BDS graduates remains inadequate.

The sample population of the follow up study were younger and comprised of more females than their counterparts in the pilot study. This finding had no effect on the level of sedation training obtained or on the number of PSA procedures undertaken by respondents. Similarly, the age and health status of children receiving PSA was unchanged. In both studies, respondents performed PSA on healthy children and children with mild systemic disease. The SASA paediatric PSA guidelines recommend a dedicated SP for any sedation of children with comorbidities [1].

Despite the conclusion of the pilot study and the intentional changes made to the anaesthetic curriculum of Wits BDS undergraduates, there has not been a deliberate response among graduates to acquire APLS/PALS certifications or paediatric sedation training. Some graduates have been deterred from performing the PSA themselves, as evidenced by an increase in the employment of anaesthetists and sedation trained medical practitioners (52% to 67%) ($p = 0.023$) and a reduction in single operator-sedation practice (46% to 22%). This change is in accordance with the SASA paediatric PSA guidelines, which recommend that a dedicated SP perform the PSA in the event that the operator has no training in the administration of sedation to children.

The SASA paediatric PSA guidelines recommend that single operator-sedation practitioners be allowed to perform both roles if the procedure is less than 30 minutes and the level of sedation does not exceed minimal sedation or anxiolysis [1]. It is not clear from the study whether the 22% of Wits BDS graduates who perform both the operation and PSA are adherent to these criteria. The follow up study revealed practices which mandate the presence of a dedicated SP, in accordance with SASA paediatric PSA guidelines. These include the administration of intravenous drugs other than 0.1mg/kg of midazolam, a combination of drugs used, deep sedation and general anaesthesia performed, operators untrained in the sedation of children or resuscitation thereof and the sedation of children with comorbidities [1]. However, respondents' identification as a single-operator practitioner and sedation practices were not linked or compared. This is a limitation of the questionnaire design.

There was no change in the number of documented pre-sedation assessments. In both studies 17% of SP's responsible for PSA did not document any pre-sedation assessment. The SASA paediatric PSA guidelines recommend a documented medical history, weight and height of the child and identification of any significant underlying medical disorders [1]. In the follow up study, 95% of respondents reported obtaining written informed consent from the patient's caregiver before performing PSA. This was a statistically significant increase from 76% in

the pilot study ($p = 0.003$). This improvement is adherent to the SASA paediatric PSA guidelines.

SASA recommend specific fasting guidelines for any advanced sedation technique, including dissociative and non-dissociative techniques and deep sedation. These guidelines include: clear fluid 2 hours preoperatively, breast milk 4 hours preoperatively and formulae feeds and solids 6 hours preoperatively. The guidelines also acknowledge that for a procedure to be completed safely, deep sedation is often needed for which advanced sedation techniques are required [1]. The follow up study questioned Wits BDS graduates about the fasting period from the time of solids only and did not include clear fluids and breast milk in the survey. This is a limitation of the questionnaire design.

The number of respondents who starve their patients for 6 hours following a meal for procedures performed with PSA has increased significantly from 24% to 48% ($p < 0.001$). However, less than half of respondents starve children for an appropriate period of time and it appears that there is a lack of knowledge regarding the recommended fasting periods in the SASA paediatric PSA guidelines. There is a trend away from insufficient starvation times (63% to 26%) and towards excessive starvation times (13% to 26%). It is likely that improved informed consent acquisition and education about aspiration risk, is associated with the improvements found in starvation adherence.

Paediatric fasting guidelines published in the European Journal of Anaesthesia in 2022, recommend children fast for 1 hour following clear fluid intake and 3 hours following breastmilk. The guidelines state that prolonged fasting time may increase ketone body production and also result in lower intraoperative systolic blood pressure [9].

According to the SASA paediatric PSA guidelines, the “minimum monitoring standard” for ASA 1 and 2 patients is pulse oximetry and non-invasive blood pressure. The guidelines stipulate that clinical monitoring alone may suffice for minimal sedation, but for all other levels of sedation both clinical and electronic monitoring must be used. During basic sedation techniques where one drug is used, intermittent electrical assessment is sufficient, but for prolonged procedures both pulse oximetry and non-invasive blood pressure monitoring are mandatory [1].

Besides temperature monitoring, there was an increased use of all of the listed monitoring methods between the pilot and follow up studies, most noticeably in the use of pulse oximetry (54%-86%). Between studies, the number of respondents who reported not using any monitoring equipment decreased from 41% to 8%. It was not established if the 8% who do not use monitoring equipment only practiced basic techniques and minimal sedation. The follow up study revealed that 46% of respondents do not monitor blood pressure, 60% do not monitor ECG, 68% do not monitor capnography, 82% do not use a stethoscope to assess respiration and 91% do not record temperature.

The SASA paediatric PSA guidelines indicate that propofol has a small margin of safety and that deep sedation, airway obstruction and apnoea occur rapidly and unpredictably with its use [1]. The guidelines therefore recommend that propofol “only be used by experienced sedation practitioners with anaesthetic training, who are skilled in the airway management of children and in a facility that meets all criteria laid out in the guidelines”, these criteria pertain to availability of basic equipment.

The follow up study revealed an increased use of midazolam (69% to 78%), propofol (27% to 60%), ketamine (25% to 56%) and clonidine (0% to 21%). The use of these agents is in

keeping with international practices, as illustrated in a systematic review of the methods of sedation for dental procedures [10]. Remimazolam was not included in the follow up study as an agent for sedation, however it is gaining popularity as a sedative agent for dental procedures internationally after a randomized control trial concluded it had fewer complications and better patient satisfaction than midazolam [11].

There was an increase in the intravenous route of administration (46% to 75%). The follow up study revealed a 34% decrease in the performance of minimal sedation, a 35% increase in the performance of deep sedation and a 13% increase in the performance of general anaesthesia. In both studies, only 20% of respondents use one drug for sedation, the remaining 80% use a combination of two or more drugs constituting advanced sedation techniques. The follow up study found that 60% of respondents use propofol and that 65% use a trained SP or an anaesthetist. It is noteworthy that there is a correlation between the involvement of anaesthetists and sedation trained medical practitioners and the administration of advanced sedation techniques, reaching greater depths of sedation and even general anaesthesia.

The SASA paediatric PSA guidelines stipulate that because deep sedation is often needed to perform procedures safely, and the level of sedation is often difficult to predict, monitoring of the level of sedation is "of utmost importance". The guidelines recommend using the University of Michigan Sedation Scale [1]. In both studies, the most common method of monitoring depth of sedation was through assessing patient's responses to commands, touch, or pain at regular intervals. Only 37% of respondents use formal sedation scales and 17% do not assess the level of sedation at all. The use of Bispectral index monitoring decreased from 16% to 10%. In 2023, a study titled "Application of Bispectral Index System (BIS) Monitor to Ambulatory Pediatric Dental Patients under Intravenous Deep Sedation" looked at 206 children between 2 and 8 years old undergoing deep sedation via propofol TCI and found significant reductions in adverse events and time to discharge in patients who were monitored using BIS [12].

There was a statistically significant increase in the number of respondents who reported having experienced a sedation related complication in the follow up study (2% to 26% of respondents, $p < 0.001$). None of the sedation related complications resulted in cardiac arrest or death. The most frequently experienced sedation related complications were oxygen desaturation, vomiting, airway obstruction and apnoea. The follow up study found that the depth of sedation achieved has increased without a corresponding increase in the use of sedation scales and that sedation related complications have increased significantly. The absence of fatal complications or permanent morbidity is in keeping with international findings. However, the incidence of nausea and vomiting in the follow up study is higher than that reported in international literature. This may be the result of prolonged fasting times. In a retrospective cohort study in 2022, the incidence of sedation related complications was studied in 250 children who underwent deep sedation with midazolam and propofol for a dental procedure. There were 5 cases of laryngospasm and 17 cases of mild hypoxia requiring bag mask ventilation. There were no reports of haemodynamic instability or death and there were no reports of post operative nausea and vomiting.

Despite a trend of increasing procurement of airway and emergency equipment in the follow up study, adherence to the SASA paediatric PSA guidelines remains inadequate [1].
The follow up study revealed that 28% of respondents do not have an oxygen supply, 20% do not have face masks, 41% do not have bag-mask ventilation devices, 55% do not have oropharyngeal or nasopharyngeal airways, 61% do not have laryngoscope sets and 62% do

not have endotracheal tubes. Furthermore, 52% do not have access to a defibrillator and 50% do not have any means of recording blood glucose levels. Although an improvement from 20% in the pilot study, 8% of Wits BDS graduates who perform paediatric dental chair PSA do not have any of the equipment recommended in the SASA paediatric PSA guidelines.

Compared to the pilot study, respondents in the follow up study reported increased availability and stocking of all of the listed emergency drugs. The number of respondents who indicated that they do not keep any of the emergency drugs recommended in the guidelines, decreased from 43% to 23%. Despite the positive trend, 70% do not keep succinylcholine, 25% do not keep adrenaline, 50% do not keep atropine, 67% do not keep naloxone and 72% do not keep flumazenil. The SASA paediatric PSA guidelines recommend that all of the above-mentioned drugs be kept in stock. Furthermore, it is recommended that "at least 10 ampoules of adrenaline be kept and that specific antagonists must be immediately available when SPs administer opioids or benzodiazepines for sedation, regardless of the route of administration" [1]. The American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) PSA guidelines, stated that the incidence of adverse events is contributed to by the lack of appropriately sized equipment for airway management and venous access, as well as the lack of proper medicine and reversal agents [6].

There was a statistically significant improvement in the use of staffed recovery areas between the pilot study and the follow up study (58% to 85%). The number of respondents who indicated that they do not utilise any form of postoperative monitoring has decreased from 38% to 5% ($p < 0.001$). The SASA paediatric PSA guidelines stipulate that, "after the procedure is complete, monitoring must continue until the child is fully recovered. Vital signs (blood pressure, heart rate, respiratory rate, oxygen saturation, level of consciousness and pain levels) must be measured and documented at regular intervals on a post sedation monitoring chart" [1].

Despite the intervention between 2016 and 2021, there has not been an improvement in awareness of the SASA paediatric PSA guidelines, only 34% of respondents in the follow up study were aware of the guidelines. Nineteen percent of Wits BDS graduates were familiar with the pilot study published in the SAMJ in 2015. A similar number of respondents in both studies (82% in the pilot and 91% in the follow up study) indicated that they would be interested in attending CPD accredited sedation training.

While the results of this study show some modest improvements in the practice of paediatric dental chair PSA and guideline adherence, they support the conclusion of the pilot study: there is a concerning lack of guideline adherence. Improvements in practice have been influenced by the increasing involvement of sedation trained medical practitioners and anaesthetists and perhaps retention of some of the safe sedation principles taught at an undergraduate level. However, a decade later, there are no significant improvements in the level of sedation training of dentists themselves, nor is there increased awareness of the SASA paediatric PSA guidelines.

Future studies should determine if there has been a change in paediatric dental chair PSA practice and guideline adherence among dentists in Gauteng and whether the increased involvement of sedation trained medical practitioners and anaesthetists is a common trend or unique to Wits BDS graduates from 2016-2021.

A strength of this study has been the validity with which the sample populations in the pilot and follow up studies have been compared. The survey tool was replicated from the pilot study and despite some demographic differences among sample populations, their level of

training was unchanged and the paediatric population receiving PSA was comparable in number, age and health status. This allowed for the achievement of all primary and secondary objectives. The response of 90% of eligible participants (68% of which practice paediatric dental chair PSA and consented to completing the survey) has strengthened the power and credibility of the study results.

A limitation of the study was that although anonymous, participants knowingly represent Wits BDS graduates from 2016 to 2021. This is a permanent association maintained by participants who therefore may not have felt comfortable providing answers that would present themselves in an unfavourable manner. Thus, the reliability of the survey may have been negatively impacted. Not all participants answered every question and some questions had options that were not mutually exclusive, this limitation prevented the determination of the statistical significance of some changes found between the pilot and the follow up study.

Conclusion

This study found that there is still a lack of adherence to recommended safety standards in the SASA paediatric PSA guidelines among Wits BDS graduates from 2016 to 2021. The study has highlighted a need for postgraduate accredited paediatric sedation training and the ongoing audit of paediatric dental chair PSA for quality assurance.

Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data is not publicly available due to privacy or ethical restrictions. The findings of this study will be made available to all participants upon completion.

Funding statement

No funding was received for the conduction of this study.

Conflict of interest disclosure

There are no conflicts of interest to declare.

Ethics approval statement

Ethics approval was granted by the Wits Human Research Ethics Committee (Medical) (Reference R14/49) and permission granted by the WITS Office of Deputy Registrar.

Participant consent statement

Completion of the questionnaire implied consent to participate in the study.

Author Contributions

Corresponding Author: Dr TM Tarlton.

Academic writing

Postgraduate, Ethics and Deputy Registrar Office approval submission

Data collection

Supervisor: Dr F Bham

Author of original study published in SAMJ 2015 [7].

Overseer of Postgraduate, Ethics and Deputy Registrar Office approval submission.

Advisor and editor of academic writing.

Supervisor: Dr C Anamourlis

Overseer of Postgraduate, Ethics and Deputy Registrar Office approval submission.

Advisor and editor of academic writing.

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Section 4: Proposal

Paediatric dental chair Procedural Sedation and Analgesia: A follow up study.

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Content's page:

1. **Introduction**
2. **Problem statement**
3. **Aim**
4. **Objectives**
5. **Research assumptions**
6. **Demarcation of study field**
7. **Ethical considerations**
8. **Data collection**
    - **8.1 Research design**
    - **8.2 Study population**
    - **8.3 Study sample**
        - **8.3.1 Sample method**
        - **8.3.2 Sample size**
        - **8.3.3 Inclusion and exclusion criteria**
    - **8.4 Collection of data**
9. **Data analysis**
10. **Significance of the study**
11. **Validity and reliability of the study**
12. **Potential limitations of the study**
13. **Project outline**
14. **Financial plan**
15. **References**
16. **Appendices**

1. Introduction

"Procedural sedation and analgesia" entails the administration of medication to facilitate diagnostic and therapeutic procedures, that otherwise would have to be added to overbooked theatre lists [1]. The objective of procedural sedation and analgesia (PSA) is to reduce a child's fear and anxiety; provide effective pain control and prevent movement; and to decrease awareness and provide amnesia. This is achieved whilst maintaining the child's consciousness and co-operation [1]. PSA is performed in a safe environment, whilst maintaining control of the child's physiological parameters and a patent airway, thereafter returning the child to a state in which safe discharge is possible [1].

An increasing number of medical and surgical procedures being performed outside of the theatre environment, combined with the need to meet the ethical and social imperatives to dimmish pain, alleviate anxiety and optimize patient comfort during a procedure, has led to the world-wide practice of PSA [2]. Different publications have recorded a low incidence of serious adverse events and a relatively low risk to PSA, yet continue to define the assessment, management and rescue of the paediatric airway as a crucial competency of the sedation practitioner [3,1]. The greatest risk is respiratory depression, which if not recognized and properly treated, can lead to hypoxia and possibly death or permanent neurological injury [4].

International sedation guidelines support sedation training, as a lack of formal training has been found to contribute to sedation related adverse events [5]. The South African Society of Anaestheisologists (SASA) guidelines for paediatric procedural sedation and analgesia (PSA) for 2021, categorize adverse events as follows [1]:

- Lesser adverse events (a short period of oxygen desaturation).
- Standard or moderate adverse events (lowest oxygen saturation at 75% or lasting longer than 60 seconds).
- Critical adverse events (permanent neurological injury, admission to hospital, CPR and tracheal intubation or death).

In 2016 the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) PSA guidelines, highlighted factors that contribute to the safe administration of PSA and the incidence of adverse events. They include the following [6]:

- Administration of sedation medication without the safety net of medical or dental supervision.
- Careful pre-sedation evaluation of medical or surgical conditions.
- Appropriate fasting for elective procedures and a discerning depth of sedation for non-starved emergencies.

- Focused airway examination for anatomical causes of potential obstruction.
- A clear understanding of the medications pharmacokinetic and pharmacodynamic effects and drug interactions.
- Appropriate training and skill to identify and rescue a compromised airway.
- Age and size appropriate equipment for airway management and venous access.
- Appropriate medications and reversal agents.
- Sufficient staff to carry out the procedure and monitor the patient.
- Appropriate physiological monitoring during and after the procedure.
- Properly equipped and staffed recovery area.
- Recovery to the pre-sedation level of consciousness before discharge.
- Appropriate discharge instructions.

SASA paediatric PSA guidelines for 2021 support the same factors and would add inappropriate patient selection and procedure suitability for sedation as contributors to adverse events [1].

International guidelines have focused on these factors to promote the safe practice of paediatric PSA. In 2021, Finland, a country without paediatric PSA guidelines, launched a national survey revealing variable practices in paediatric PSA and patient monitoring [7]. The survey found that only one third of sedation practitioners had undergone formal training. Only 39% of units practicing paediatric PSA recorded data on sedation related adverse events. There was no objective measurement of sedation depth and whilst 78% of sedation practitioners used pulse oximetry, only 39% used non-invasive blood pressure monitoring (NIBP) and 28% used electrocardiogram (ECG) recordings. The survey did reveal that 98% of sedation practitioners had supplemental oxygen available and 92% had appropriate ventilation equipment [7].

In the Netherlands, two sedation related paediatric fatalities led to the 2009 nationwide investigation into the adherence of general paediatricians to safety standards and PSA guidelines [8]. Four areas of patient sedation were assessed, namely: pre-sedation assessment, monitoring during procedural sedation, recovery after procedural sedation and facilities and competencies for emergency and rescue. These were each scored 0-10. A score of more than eight represented satisfactory adherence whilst a score of less than 6 represented unacceptably low adherence to guidelines. Only a minority achieved a satisfactory adherence status (>8), full adherence was rare. Large numbers of respondents scored below six. The survey concluded that potentially unsafe PSA practices are common under Dutch general paediatricians, despite availability of guidelines [8].

In 2015, SAMJ published a study titled “Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa”, which found alarming, self-reported figures of guideline

non-adherence [9]. The study found that 44% of Gauteng based dentists practised paediatric PSA. The majority of patients sedated were between one and five years old. Whilst most sedation practitioners in these dental rooms intended to achieve mild to moderate sedation, some administered deep sedation and even general anaesthesia. The findings included the following figures [9]:

- 83% of sedation practitioners (SP's) documented pre-sedation assessment and 75.6% documented informed consent.
- 28.1% of SP's used a combination of three or more agents.
- 41.3% of SP's did not use any monitoring equipment.
- 41.3% of SP's were responsible for the procedure as well as the sedation.
- 43.2% of SP's did not keep any recommended emergency drugs.
- 19.6% of SP's did not have any emergency resuscitation equipment available.
- 78% of SP's had supplemental oxygen, (71% had facemask oxygen).
- 47.8 % of SP's had access to Bag-mask-ventilation
- 34.8% of SP's had access to oropharyngeal and nasopharyngeal airways.
- 30.4% of SP's had access to IV cannulas for IV access.
- 30.4% of SP's had access to laryngoscopy sets.
- 17.4% of SP's had access to defibrillators.

Following this publication, SASA released the updated paediatric PSA guidelines for 2016. The WITS Department of Anaesthesiology: Dental portfolio and the WITS Dental Science school intervened by placing emphasis on "safe sedation principles", in the form of lectures during the dental student's sedation module. The SASA paediatric PSA guidelines were introduced to the dental students with the hope that greater awareness of the guidelines may result in improved guideline adherence. To date there has been no follow up study to measure the effect of this intervention.

Literature confirms the need for sedation training and has recommendations about what it should contain. In the Emergency Department setting, the study "Development and implementation of an education and credentialing program to provide safe paediatric procedural sedation" concluded that training programs were "found useful" by sedation practitioners and that such programs should include the following [10]:

- Sedation manual.
- Lectures.
- Treatment order forms and checklists.
- Parent consent and counselling skills.

In 2009, a report from the Pediatric Sedation Research Consortium, published in Pediatric Anaesthesiology, documented the incidence and nature of sedation related adverse events during procedural sedation outside of the operating room [11]. After confirming that it is unlikely to have “serious adverse events”, the study found that safety depends on a sedation practitioners’ ability to handle “less serious adverse events”. They recommend, therefore, that training sedation practitioners should focus on the management of “more common” adverse events, including the following:

- Desaturation below 90% for more than thirty seconds.
- Central apnoea and airway obstruction.
- Laryngospasm.
- Excessive secretions.
- Vomiting.

The national survey of paediatrician’s adherence to PSA safety standards in the Netherlands, which found potentially unsafe PSA practices to be common, recommended that guidelines should include a goal directed plan for continuous quality assurance and improvement, and repeated measurements of adherence to guidelines.

This recommendation is repeated in the SASA Paediatric PSA guidelines for 2021, which stipulate that in accordance with good clinical governance [1]:

- All Sedation Practitioners (SP’s) are required to be registered as Medical Practitioners by the Health Professions Council of South Africa (HPCSA) and comply with current safety regulations of the HPCSA.
- SP’s should have clinical accountability that includes evaluation of expertise, clinical appraisal and implementation of SASA guidelines on PSA for children. This includes keeping a logbook of cases performed under sedation and documentation of adverse incidents and accidents.
- SP’s should have in house training sessions for the sedation team.

It is also recommended that:

- Facilities undergo inspection to comply with quality assurance policies and procedures.
- SP’s must have an appraisal which is overseen by the Society of Sedation Practitioners of South Africa (SOSPOSA) every two years. Where after they will receive a certificate of good standing.
- All sedation staff should keep a record of Basic Life Support (BLS) certification.

- SP's should keep record of Pediatric Advanced Life Support (PALS) and Advanced Cardiac Life Support (ACLS) certification.

Since the publication of "Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa", there has not been a follow up study amongst sedation practitioners in the dental rooms of WITS Dental Science school graduates.

2. Problem statement

Complications arising from PSA are rare. When complications do occur, they may be severe, resulting in death or permanent neurological injury. Airway complications account for most of these and are preventable if properly identified and managed [12]. The SASA paediatric PSA guidelines provide instructions for the safe administration of PSA and the management of complications [1]. The original study published in the SAMJ in 2015 titled, "Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa", concluded that paediatric dental chair PSA is practised by 44.13% of Gauteng based dental practitioners and that there is a concerning lack of adherence to recommended safety standards [9]. Following this publication, SASA released the updated paediatric PSA guidelines for 2016. The WITS Department of Anaesthesiology: Dental portfolio and the WITS Dental Science school intervened by placing emphasis on "safe sedation principles" in the form of lectures, during the dental student's sedation module. The SASA paediatric PSA guidelines were introduced to the dental students with the hope that greater awareness of the guidelines may result in improved guideline adherence. To date there has been no follow up study to measure the effect of this intervention.

3. Aim

The aim of this study is to determine if there has been a change in paediatric dental chair PSA practice and guideline adherence amongst dentists graduating from WITS Dental school after the publication of "Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa" in 2015.

4. Objectives

Primary objectives:

- To identify WITS Dental Science school graduates between 2016-2021.
- To determine what proportion of these dentists, utilize paediatric dental chair PSA in their dental practice.
- To determine the level of training and qualification of the sedation practitioner administering PSA in the dental rooms of WITS Dental Science school graduates.

- To define the current practice of paediatric PSA in the dental rooms of WITS Dental Science school graduates.
- To determine adherence to the 2021 SASA paediatric PSA guidelines.
- To compare findings with those published in the 2015 publication: “Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa”.

Secondary objective:

- To determine the occurrence of complications of paediatric PSA.
- To determine WITS Dental Science school graduate’s awareness of the 2015 publication: “Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa” and of SASA Paediatric PSA guidelines.
- To determine how many of the WITS Dental Science school graduates practising paediatric PSA, have attended sedation training courses outside of the WITS curriculum or feel further sedation training is needed.

5. Research assumptions

a. **Child or Paediatric patient:** An individual 12 years or younger falls into this category for the purpose of this study. A patient in this report refers to a child.

b. **Dental practice or practice:** Refers to the dental rooms. The dental practitioner may or may not be the person responsible for PSA administration in this practice.

c. **Dental practitioner**: The person who performs the dental procedure, but may or may not be the person responsible for PSA administration in a particular dental practice.

d. **Procedural sedation and analgesia (PSA):** An intervention which achieves effective control of pain, anxiety and movement in children undergoing procedures. Decreased awareness and amnesia are added advantages and may include a continuum of altered state of consciousness, varying from minimal sedation and anxiolysis to deep sedation [1].

e. **SurveyMonkey™**: A web-based company which enables the online design and creation of customized questionnaires. It serves as the survey platform, collects and analyses data, and ensures the security and anonymity of participants [13].

This follow up study will use the 2021 Paediatric Procedural Sedation and Analgesia guidelines as the source of reference. The Guidelines describe the depth and type of sedation as follows [1]:

f. **Minimal sedation and anxiolysis:** Minimal sedation is a drug-induced state during which the patient responds normally to verbal commands. Cognitive function may be impaired, but ventilatory and cardiovascular functions are unaffected.

g. **Moderate sedation and analgesia:** Moderate sedation is a drug-induced depression of consciousness during which the patient responds purposefully to verbal commands, either alone or accompanied by light, tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate.

h. **Deep sedation and analgesia:** Deep sedation is a drug-induced depression of consciousness during which patients cannot easily be roused, but may respond purposefully following repeated or painful stimulation. Reflex withdrawal from a painful stimulus is not considered to be a purposeful response. Deep sedation may be accompanied by clinically significant ventilatory depression.

i. **Non-dissociative sedation:** non-dissociative sedative drugs (including opioids, benzodiazepines, barbiturates, etomidate and propofol) operate on the sedation dose-response continuum. Higher doses provide progressively deeper levels of sedation with possible respiratory and cardiovascular compromise, central nervous system depression, and unconsciousness.

j. **Dissociative sedation:** Dissociative sedation, produced by ketamine, causes a trance-like cataleptic state characterised by intense analgesia, amnesia, sedation, retention of protective reflexes (as deeper levels of sedation are reached, airway reflexes may be obtunded), spontaneous breathing and cardiovascular stability. It is believed that, when ketamine is administered in dissociative doses, it does not operate on the sedation continuum.

k. **General anaesthesia:** General anaesthesia is a drug-induced loss of consciousness during which patients cannot be roused, even by painful stimulation. The ability to maintain independent ventilatory function is

impaired. Patients require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

l. **Basic or standard sedation:** Basic or standard sedation can be defined as sedation induced by a single agent and not a combination of two or more agents. This includes inhalation of nitrous oxide (N2 O) in oxygen, where the concentration of N2 O must not exceed 50% in oxygen, or the titrated intravenous administration of midazolam to a maximum dose of 0.1 mg/kg. The use of propofol (or any other anaesthetic induction agent) is by definition an advanced sedation technique. Any advance beyond basic or standard sedation requires the patient to be fasted and a designated sedation practitioner to be present.

m. **Advanced sedation:** Advanced sedation is induced by one of the following techniques:

   i. Any combination of drugs, administered by any route; or
   ii. Any sedation administered by the intravenous route, using bolus or infusion techniques with the exception of IV midazolam to a maximum dose of 0.1mg/kg; or
   iii. Any inhalational sedation (e.g. sevoflurane), with the exception of N2O used as the sole agent in a concentration of less than 50% in oxygen.

   Advanced sedation can include both dissociative and non-dissociative techniques. Advanced sedation techniques should only be performed by those sedation practitioners who have had the necessary clinical and life-support training. Advanced sedation techniques require the attendance of a dedicated sedation practitioner and should not be performed by operator sedation practitioners.

n. **American Society of Anaesthesiologists (ASA) physical status classification [1]:**

Class 1	A normal healthy patient
Class 2	A patient with mild systemic disease and no functional incapacity
Class 3	A patient with severe systemic disease that limits activity, but is not incapacitating
Class 4	A patient with severe systemic disease that is a constant threat to life
Class 5	A moribund patient not expected to survive 24 hours with or without an operation
"E"	An emergency procedure is denoted by the letter E following the class number

6. Demarcation of study field

The study will include 2016-2021 WITS Dental Science school graduates. The study field will not be limited to those dentists practising within Gauteng only. A WITS Dental Science school graduate who is practising in a different province will be included in the study field. A list of WITS Dental Science school graduates will be provided by the Dean of WITS Dental Science school.

7. Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) and the Graduate Studies Committee of the University of the Witwatersrand.
The Head of Department at the WITS Dental Science school will be approached to access the names and contact details of WITS Dental Science school graduates from 2016-2021 and for written permission to conduct a questionnaire-based survey amongst them (see appendix 1 and 2).

The participants anonymity and confidentiality will be explained on the cover sheet of the questionnaire and ensured by the use of SurveyMonkey. Completion of the questionnaire will imply consent.

Anonymity: Only researchers and supervisors will have access to names and contact details of the dental practitioners invited to partake in the questionnaire. Names and contact details of dental practitioners will be kept secure. No identifying information will be requested on the questionnaire and participants will be allocated a study number. SurveyMonkey ensures participant anonymity.
Confidentiality: Only researchers and supervisors will have access to the raw data. SurveyMonkey captures responses of participants without record of the participants personal details or email address.

This study does not involve any patient, drug or therapeutic intervention.
Data will be stored securely for six years after completion of study on a password protected database.
Study will be conducted according to the principles of the *Declaration of Helsinki* [14] and the *South African Guidelines for Good Clinical Practice* [15].

8. Data collection

a. Research design

A prospective, contextual, descriptive survey study design will be used.

In a prospective study, variables are measured in all subjects in the same way, using identical data collection methods, without grouping subjects according to distinguishing features. This is done before the occurrence of an outcome and may identify exposure/risk in a subject as they are followed longitudinally [16]. In this study, the practice of paediatric dental chair PSA will be defined and variables measured at the time of the study and not in retrospect. All WITS Dental Science school graduates will be included in the study, without knowledge of their current practice, guideline adherence or complication rate.

A contextual study is conducted in a specific location [16]. Following the 2015 SAMJ publication, WITS Dental Science school was the location of the intervention to increase students' awareness of SASA PSA guidelines and safe sedation principles. It is in this context that this study will only include dentists who have graduated from this location (WITS Dental Science school). Graduates will not be excluded if they currently practice in another province, as they were at WITS Dental Science school at the time the intervention was implemented.

Descriptive research aims to observe and measure variables accurately in a selected population without controlling or manipulating variables. It is useful in describing trends and frequencies in a particular field to understand what, when and how something occurs, but does not establish a cause-effect relationship. It commonly takes the form of a survey, questionnaire or interview [16]. This study is descriptive because it will observe current practice of

paediatric dental chair PSA and determine the current level of guideline adherence.

b. Study population

Dental practitioners who qualified from WITS Dental Sciences school in the years 2016 – 2021 form the study population group.

c. Study sample

i. Sample method

A convenient sampling method will be used in this study [17]. Convenient sampling seeks to include those subjects who are most accessible to the researcher. WITS Dental Science school is in close proximity and has academic associations with the WITS Department of Anaesthesiology.

ii. Sample size

The sample size was determined in consultation with a biostatistician. With a population size of 150 graduates, a population proportion of 50% and a confidence interval (CI) of 95%, a response rate of 108 graduates is considered acceptable. All WITS Dental Science school graduates from the classes of 2016-2021 will be invited to participate.

iii. Inclusion and exclusion criteria

Dental practitioners who graduated from WITS Dental Science school from 2016-2021 will be invited telephonically to partake in the questionnaire. Those who decline to partake will be excluded. Those who agree to partake will be emailed the SurveyMonkey link to the questionnaire.

d. Collection of data

A literature review was conducted to identify the areas of patient safety that raise concern. The SASA guidelines [1] served as the reference for standard of care. Written permission to replicate questions from the original study was granted by co-author Dr F Bham (Appendix 1). A web-based data collection sheet was designed using SurveyMonkey (Appendix 2). This data collection sheet intentionally replicates the questions from the original study to ensure reliability and allow direct comparison. The data collection sheet will be reviewed by two anaesthesiologists to ensure validity.

The names and contact details of WITS Dental Science school graduates from 2016 to 2021 will be obtained from Human Resources with permission of the WITS Dental Science school HOD (Appendix 3 and 4). Graduates will be phoned by the author of this study and will be asked if Pediatric procedural sedation and analgesia is practised within their rooms. If the graduate indicates that PSA is practised in their dental rooms, they will be invited to participate in an online

survey and be sent a link to access the questionnaire via online host SurveyMonkey [13].

9. Data analysis

SurveyMonkey, the host for the web-based data collection sheet will store incoming data. As per the original study, descriptive statistics using frequencies and percentages will be used to analyse data [9].

10. Significance of the study

The original study concluded that a significant proportion of Gauteng-based dental practices were making use of paediatric PSA in an unsafe manner, when compared to the SASA PSA guidelines as a standard of reference [9]. The study highlighted that whilst the SASA guidelines were designed to reduce severe and preventable complications of PSA [1], a significant proportion (80%) of Dentists utilizing paediatric PSA in their practices were not aware of the guidelines [9]. It was also described that 81% desired sedation training [9]. In response to the findings, the WITS Anaesthetic departments Dental Portfolio together with the WITS Dental Science school, intervened to emphasise safe sedation principles and increase awareness of the SASA Paediatric PSA guidelines in the form of lectures, amongst dental students.

The effect of the intervention has not been measured in the time since the publication of the study. It is not known if WITS Dental Science school graduates have better awareness of the SASA Paediatric PSA guidelines. It is not known what proportion are practising paediatric dental chair PSA. It is not known whether they practice with better adherence to guidelines or if improved adherence has translated into fewer complications.

In accordance with good clinical governance, this follow-up study aims to audit current practice of paediatric dental chair PSA and determine sedation practitioner's adherence to safety standards, using the SASA Paediatric PSA Guidelines for 2021 as the source of reference. Recommendations will be made for those findings which infer potential danger to patients. Guidelines for safe paediatric PSA practice, assessment tools and safety checklists will be provided to those dental practices which do not utilise them.

11. Validity and reliability of the study

Validity is ensured by using the SASA Paediatric PSA guidelines for 2021, as the standard of reference when formulating the data collection sheet. The entire population in question (WITS Dental Science school graduates from 2016-2021) will be included in the study, strengthening the studies validity. Anonymity will be ensured.

The reliability of the study is ensured by replicating the original studies questionnaire with only small additions pertaining to updates in guidelines. The questionnaire will again be hosted online by SurveyMonkey, so that the conditions of the initial study are replicated. In this way the method will consistently measure results that are comparable.

12. Potential limitations of the study

The sample size may not be as large or comparable to the original study.
As it is a questionnaire, the study may be limited by dishonest and incomplete answers. Recollection of practice and complications will be memory based and therefore potentially limit the study.
Convenience sampling bias may limit the study as the Dental Science school in closest proximity to the WITS Department of Anaesthesia was selected as the population pool.

13. Project outline

Table: Project outline

Activity	Jun 2021	Aug 2021	Oct 2021	Feb 2022	Mar 2022	Apr 2022	May 2022	Jun 2022	Jul 2022	Aug 2022	Sep 2022
Proposal preparation											
Literature review											
Proposal submission											
Ethics approval											
Postgraduate approval											
Data collection											
Data analysis											
Draft article											
Submission											

14. Financial plan

The Department of Anaesthesia will bear the cost of printing and paper for the postgraduate approval.

Table: Financial plan

Item	Price per page	Number of pages	Copies	Total
Proposal	1	20	10	R 200
Ethics	1	10	25	R 250
Post graduate form	1	2	6	R 12
Complete report	1	100	4	R 400
Survey monkey	R4680 pa per user			R4680,00
Grand total				**R 5542.00**

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Appendices

Appendix 1: Written permission to replicate questions from the original study, granted by Dr F Bham.

Appendix 2: Questionnaire and information sheet.

Appendix 3: Letter of permission from HOD of School of Oral Sciences.

Appendix 1

Written permission to replicate questions from the original study, granted by Dr F Bham.

I, Faizal Bham , am the author of "Pediatric dental chair sedation: An audit of current practice in Gauteng, South Africa"[9], and co-author of this MMED: "Paediatric dental chair Procedural Sedation and Analgesia: A follow up study". I formally permit Dr Thomas Tarlton to replicate the questionnaire used as the data collection tool in the original study and allow for changes to be made to said questionnaire to achieve the primary and secondary objectives stated in the above proposal.

Signature:  .

at (place), Johannesburg on the 9th day of March 2022.

Appendix 2

Questionnaire: Paediatric dental chair procedural sedation and analgesia: A follow up study.

Participant Information Sheet

Study title: Paediatric dental chair procedural sedation and analgesia: A follow up study

Dear Colleague,

Good day.

Introduction

My name is Thomas Tarlton and I am an anaesthetic registrar at Wits University. I am conducting a research project as part of the requirement for the M Med degree for which I am registered. I would like to invite you to participate in this study.

Please read the information below.

Background

In 2015 the South African Medical Journal published "Paediatric dental chair sedation: An audit of current practice in Gauteng". This publication highlighted aspects of Paediatric sedation that could be improved, to ensure the safety of children having dental procedures under sedation. In 2016 the South African Society of Anaesthesiologists (SASA) published guidelines for Paediatric procedural sedation and analgesia. WITS Anaesthesia and WITS Dental Science School implemented teaching on safe sedation principles, in the form of lectures, introducing dental science scholars to the SASA Paediatric guidelines with the intention of improving awareness and adherence to these guidelines.

Study procedure

In order to determine the success or otherwise of this intervention, I would be grateful if you would complete a self-administered online questionnaire, the link to which will be sent to all willing participants. Participation is voluntary. There are no consequences to refusing to participate. You may withdraw from the study at any point up to submission of the questionnaire.

As a WITS Dental Science graduate, you are a crucial participant in the measurement of this intervention and your response to this questionnaire will enable us to determine the effect of this intervention and to identify areas in which training can be enhanced and patient safety improved. Your response will be anonymous and confidential and completion of this multiple-choice questionnaire will take approximately 15 minutes. Instructions accompany each question and definitions are provided for your convenience. Completion of the questionnaire implies consent to participate in the study. The results of this study will be made available to all participants once the study is completed.

Further information

This study is being conducted by Dr T Tarlton, Dr F Bham and Dr C Anamourlis. Responses will be collected from September - October 2022. Any queries about this questionnaire and its results can be directed to Dr Tarlton at tomtarltonanaesthesia@gmail.com or telephonically on 060 895 8586. This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research. If you have any concern over the way the study is being conducted, please

contact the Chairperson of this Committee who is Dr Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

September 2022

1. How many children are sedated in your practice per month?
    - 1-5
    - 6-15
    - 16-30
    - 31-50
    - More than 50
2. Who is primarily responsible for administering sedation in your rooms?
    - I am
    - A qualified nurse
    - A medical practitioner
    - A medical practitioner with sedation training.
    - An Anaesthetist
    - Other (please specify)
3. Do you have sedation training?
    - Yes
    - No
4. Definition:
    - **Minimal sedation/anxiolysis:** Patient responds normally to verbal commands. Cognitive function and coordination may be impaired.

      Moderate/conscious sedation: Patient responds purposefully to verbal commands either alone or in combination with light touch.

      Deep sedation: Patient cannot easily be aroused, but may respond purposefully following repeated verbal or painful stimulation.

      General anaesthesia: Patients cannot be aroused even by painful stimulation.

      How deeply are your patients sedated? More than one option may be selected. (Refer to definitions above).
    - Minimal sedation.
    - Moderate sedation
    - Deep sedation
    - General anaesthesia

5. Which patient age groups are sedated in your rooms? More than one option may be selected
    - Age <1 year
    - Age 1-5 years
    - Age 6-8 years
    - Age 9-12 years
6. Which of the following patient groups are sedated? More than one option may be selected.
    - Normal healthy children
    - Children with mild systemic disease who have no functional limitation e.g. Well controlled asthmatic
    - Children with severe systemic disease which limits activity but is not incapacitating e.g., asthmatic needing a bronchodilator
    - Children with severe systemic disease which is functionally incapacitating and a constant threat to life e.g., congenital heart disease in cardiac failure
7. Answer yes or no.
    - Are details of pre-sedation assessment documented? Yes/No
    - Is written informed consent obtained from the caregiver? Yes/No
8. How long prior to sedation, are children allowed to receive their last meal?
    - _____.
9. Which of the following drugs are used for sedation in your rooms? More than one answer may be selected.
    - Nitrous oxide
    - Midazolam (Dormicum)
    - Diazepam (Valium)
    - Fentanyl
    - Alfentanil (Rapifen)
    - Remifentanil
    - Tilidine (Valaron)
    - Morphine
    - Meperidine (Pethidine)
    - Propofol

- Ketamine
- Clonidine
- Dexmedetomidine
- Chloral hydrate
- Trimeprazine (Vallergan)
- Droperidol
- Paracetamol
- Non-steroidal anti-inflammatory drugs (NSAIDS eg ibuprofen, diclofenac, ketorolac)
- Local anaesthetic agents
- Stopayne
- Myprodol

10. A combination of how many of the above-mentioned drugs are used during most procedures? (Excluding paracetamol, NSAIDS and Local anaesthetics)
    - _____.
11. Which of the following drugs are kept in stock? More than one option may be selected.
    - Adrenaline
    - Atropine
    - Flumazenil
    - Naloxone
    - Succinylcholine
    - None of the above
12. What route(s) of drug administration is used?
    - Inhalational
    - Oral
    - Intramuscular
    - Intravenous
    - Rectal
    - Other (Please specify)
13. Who is responsible for patient monitoring?
    - I am

- A nurse
- A medical practitioner
- A medical practitioner with sedation training
- An anaesthetist
- Other (please specify)

14. Which of the following equipment is used for the purpose of patient monitoring? More than one option may be selected.
    - Pulse oximetry
    - Non-invasive blood pressure
    - Capnography
    - Precordial stethoscope
    - ECG
    - Thermometer
    - Sedation monitoring chart
    - None of the above
15. How is level of consciousness or depth of sedation monitored? More than one option may be selected.
    - Bi-spectral index monitoring
    - Using a sedation scale
    - Response to command/touch/pain assessed at a regular time interval
    - Response to command/touch/pain only when there is concern that the patient is too deeply sedated
    - Level of consciousness monitoring is not necessary in my setting
16. Which of the following equipment is available in your rooms? More than one option may be selected.
    - Face masks
    - Laryngoscope set
    - Endotracheal tubes
    - Oropharyngeal and/or nasopharyngeal airways
    - End-tidal carbon dioxide monitoring device
    - Oxygen supply
    - Bag-valve-ventilation device

- Defibrillator
- Intravenous cannula
- Intravenous fluids
- Blood glucose monitoring device
- None of the above

17. Are patients monitored in a staffed recovery area prior to discharge?
    - Yes
    - No
    - Other (please specify)
18. Which parameters are assessed during recovery or prior to discharge at your facility? More than one option may be selected.
    - Level of consciousness
    - Respiration
    - Oxygen saturation
    - Movement
    - Temperature
    - Pain
    - Bleeding
    - Ability to drink
    - Nausea/vomiting
    - Availability of a responsible caregiver
    - None of the above
19. Have any paediatric patients experienced any sedation-related complications in your rooms?
    - Yes
    - No
20. Which complication have they experienced? More than one option may be selected.
    - Airway obstruction
    - Apnoea
    - Oxygen desaturation
    - Vomiting
    - Aspiration

- Hypotension
- Anaphylaxis
- Other allergic reactions
- Neurological injury
- Cardiac arrest
- Death
- Other (please specify)
- None of the above

21. Definition:
    - **BLS:** Basic Life Support

      APLS: Advanced Paediatric Life Support

      PALS: Paediatric Advanced Life Support

      SOSPOSA: Society of Sedation Practitioners of South Africa

      SASA PSA guidelines: Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children: 2016 (Developed by the South African Society of Anaesthesiologists)

      Indicate Yes or No. (Refer to the above definitions if necessary)
    - Are you BLS certified? Yes/No
    - Are you APLS/PALS certified? Yes/No
    - Are you a member of SOSPOSA? Yes/No
    - Are you aware of the SASA paediatric PSA guidelines? Yes/No
22. If you make use of any alternative sedation guidelines, please specify which guidelines you use.
    - _____.
23. Are you aware of the study, “Paediatric dental chair sedation: An audit of current practice in Gauteng, South Africa”, which was published in the SAMJ in 2015?
    - Yes
    - No
24. What is your age in years?
    - _____.
25. What is your gender?

- _____.

26. Have you ever attended a CPD accredited sedation training course?
    - Yes
    - No
27. Would you benefit from further sedation training?
    - Yes
    - No

Thank you for completing this survey.

Appendix 3.

Letter of permission from Dental Science school HOD.

School of Oral Health Sciences
Faculty of Health Sciences

WITS UNIVERSITY

P Bag 3, Wits 2050, South Africa • Fax 0865534805 • Telephone 011 488-4866 • email: Joy.Shackleton1@wits.ac.za

26 April 2022

Dr T Tarlton
A0041634
Registrar : Anaesthetics

Dear Dr Tarlton

Re: Permission to conduct research on graduates from the School of Oral Health Sciences

This letter provides you with permission to conduct research by surveying SOHS graduates from 2016 – 2021 for your study entitled : "Paediatric dental chair Procedural Sedation and Analgesia: A follow up study".

This permission is subject to the granting of an Ethics Clearance, and to the adherence to the attached memorandum from the University Registrar's Office : "Procedures for Obtaining the University Registrar's Permission for the Use of University Student or Staff as Research Participants".

Kindly note that the School does not hold the contact details of graduates.

Yours sincerely

Joy Shackleton

Prof JL Shackleton
Acting Head: School of Oral Health Sciences

Cc Dr M Turton
Ms N Makubalo

Section 5. Annexures

5.1 Ethics approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG	HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research and Innovation)

TO:	Dr TM Tarlton School of Clinical Medicine Department of Anaesthesia Medical School University E-mail: tom.m.tarlton@gmail.com
CC:	Supervisor: Drs F Bham and C Anamourlis <faizalbham@gmail.com> and <HREC-Medical Research Office@wits.ac.za>
FROM:	Mr Iain Burns Human Research Ethics Committee (Medical) Tel: 011 717 1252 E-mail: Iain.Burns@wits.ac.za
DATE:	2022/09/09
REF:	R14/49
PROTOCOL NO:	**M220552** (This is your ethics application reference number. Please quote it in all enquiries, oral or written, relating to this study.)
PROJECT TITLE:	*Paediatric dental chair procedural sedation and analgesia: A follow up study*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to Government funding of the University.

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UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R49 Dr TM Tarlton

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M220552

NAME: (Principal Investigator)	Dr TM Tarlton
DEPARTMENT:	School of Clinical Medicine Department of Anaesthesia Medical School University
PROJECT TITLE:	*Paediatric dental chair procedural sedation and analgesia: A follow up study*
DATE CONSIDERED:	2022/05/27
DECISION:	Approved unconditionally
CONDITIONS:	
NOTE:	If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>
SUPERVISOR:	Drs F Bham and C Anamourlis
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2022/09/09

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **May** and therefore reports and re-certification will be due in the month of **May** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

20-09-2022
Date

5.2 Office of Deputy Registrar permission letter.

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

OFFICE OF THE DEPUTY REGISTRAR

15 November 2022

Thomas Mark Tarlton
Student Number (363410)
Master of Medicine in Anaesthesia
Faculty of Health Sciences

TO WHOM IT MAY CONCERN

"Paediatric dental chair procedural sedation and analgesia: A follow up study ."

This letter serves to confirm that the above project has received permission to be conducted on University premises, and/or involving staff and/or students of the University as research participants. In undertaking this research, you agree to abide by all University regulations for conducting research on campus and to respect participants' rights to withdraw from participation at any time.

If you are conducting research on certain student cohorts, year groups or courses within specific Schools and within the teaching term, permission must be sought from Heads of School or individual academics.

Ethical clearance has been obtained. (Protocol number: M220552)

Research Expiration: (09 September 2027)

Nicoleen Potgieter
University Deputy Registrar

5.3 Wits post-graduate studies approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

23 March 2022
Person No: 363410
PAG

Dr TM Tarlton
561 Amsterdam Estate
Olivedale
2188
South Africa

Dear Dr Thomas Tarlton

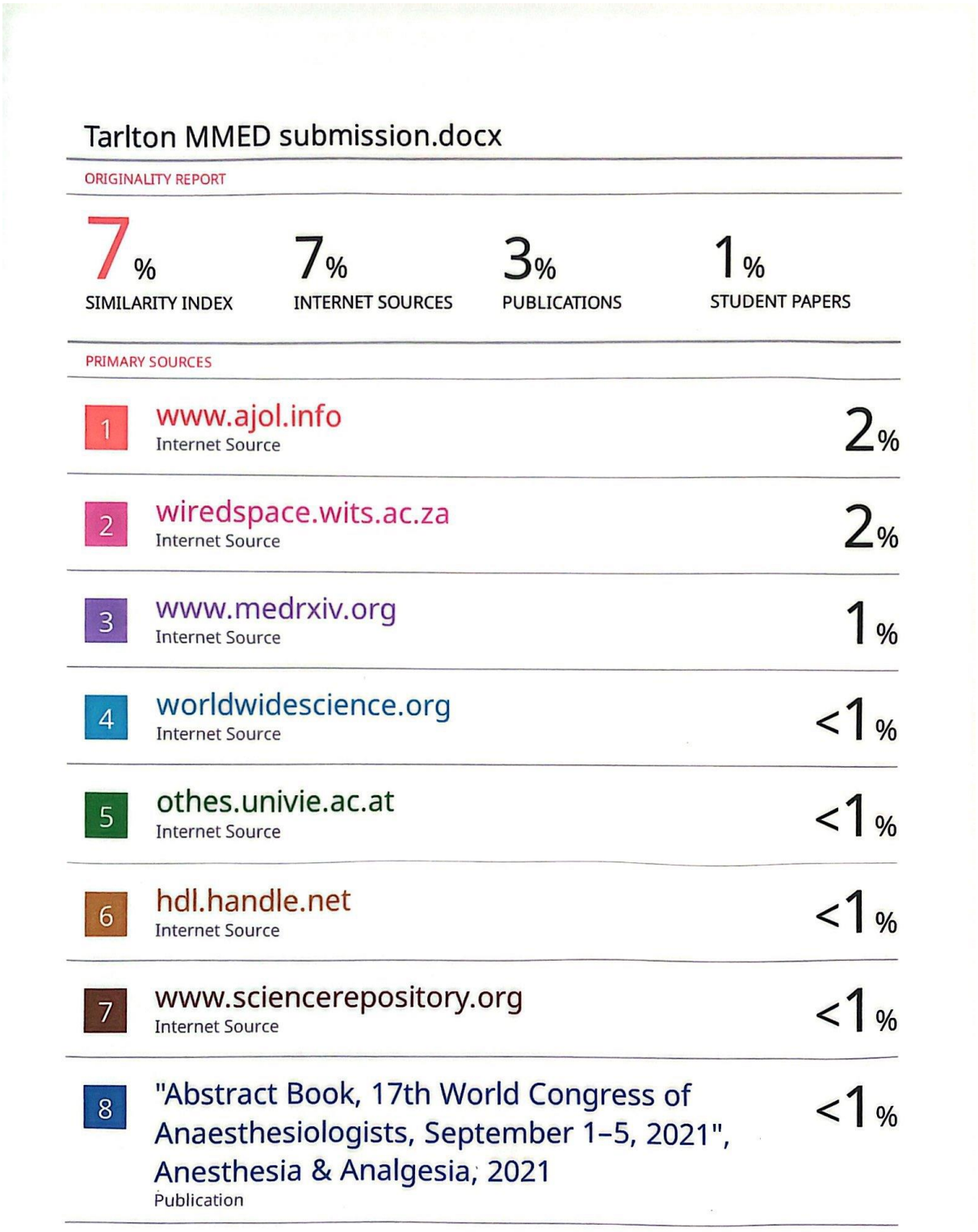
Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *Paediatric dental chair procedural sedation and analgesia: A follow up study* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

5.4 Turnitin report



Tarlton MMED submission.docx

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