

Pain modulation by audiovisual distraction during local cystoscopy

Dr Amadadin Alhlib

MBBS Almargeb University, Libya

Student number: 1304354

Supervisors:

1. Prof. M Haffejee

MBBCH, FCS (Urology) SA

Head of Urology, University of the Witwatersrand

2. Dr Marietha Nel

BSc, BSc Hon (Pharmacol), MSc, PhD

Senior Medical Scientist

Department of Surgery, University of the Witwatersrand

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the degree of MMED written according to the

Wits Medical School FHS submissible format.

23 June 2021

DECLARATION BY THE CANDIDATE

I, Amadadin Alhlib, herewith declare that this report is the product of my own research and that it has not previously been submitted for any degree or examination either at the University of the Witwatersrand or at any other university.

Amadadin Alhlib

Signature: 

Date: 23 June 2021

DEDICATION

To the soul of my Grandfather, Grandmother and my Aunt.

ACKNOWLEDGEMENTS

On completion of this study, I would like to thank my supervisors, Professor Mohamed Haffejee and Dr Marietha Nel, I highly appreciate their support and guidance during my research.

My appreciation also goes to the nurses at the urology theatre of the Charlotte Maxeke Johannesburg Academic Hospital for their assistance during the research. I wish to thank the workers and my colleagues at the Charlotte Maxeke Johannesburg Academic Hospital for their support.

I also acknowledge with great appreciation the encouragement of my family, particularly my wife and children.

Last but not least, a very special and heartfelt thank you to Prof Ahmed Adam for giving me the main idea of my research.

CONTENTS	PAGE
DECLARATION BY THE CANDIDATE.....	2
DEDICATION.....	3
ACKNOWLEDGEMENTS.....	4
TABLE OF CONTENTS.....	5
LIST OF FIGURES.....	6
ABBREVIATIONS	7
Chapter 1 Expanded MMed literature review.....	8
Chapter 2 Urology Annals Instructions to authors	18
Chapter 3 Article	
3.1 Cover page as required by the journal.....	27
3.2 Submissible research article	28
Abstract	28
Introduction.....	29
Materials and methods.....	30
Results.....	32
Discussion	34
Conclusion	35
Limitations	36
References.....	36
Tables and figures legends	
Figure1: Patients who had cystoscopies.....	38
Figure 2: Numbers of early complications post cystoscopy.....	38
Table 1: Comparison of pain levels during cystoscopy related to previous procedures	38

Chapter 4 Appendices:

Appendix I Submitted and approved protocol.....	40
Appendix II Approval of research protocol letter.....	52
Appendix III Patient's questionnaire.....	53
Appendix IV Doctor's questionnaire.....	56
Appendix V Ethics clearance certificate.....	58
Appendix VI Turnitin report.....	59
Appendix VII Copy of the published article in Annals of Urology.....	60

ABBREVIATIONS

AVD Audiovisual Distraction

CMJAH Charlotte Maxeke Johannesburg Academic Hospital

VAS Visual Analogue Scale

SD Standard Deviation

IASP International Association for the Study of Pain

PI Principle investigator

Pain modulation by audiovisual distraction

during local cystoscopy

Chapter 1: Expanded literature review

Cystoscopy is one of the most common urological procedures used for either diagnostic, therapeutic or for surveillance purposes. It is an endoscopic inspection of the urothelium lining of the urethra, prostate and urinary bladder. It may be performed under local or general anaesthesia. Cystoscopy is indicated for patients who present with haematuria, recurrent urinary tract infection and lower urinary tract symptoms or for surveillance after urinary bladder tumour resection.

Initially rigid cystoscopy was used before moving to flexible cystoscopy, which was introduced by Tsuchida and Sugawara in 1973.¹ Both devices have the same efficacy to diagnose bladder pathologies.^{2, 3} Despite wide use of the flexible device, the rigid device is still used in many institutions because of its simplicity, lower cost and lower maintenance in comparison to the flexible scope.⁴

Local cystoscopy is performed in the lithotomy or supine position. After application of the local anaesthetic, usually 2% remicaine jelly, the procedure involves introducing the scope through the urethra while inspecting the route into the bladder, using irrigation to achieve better visualisation. The procedure is associated with pain and discomfort, whether it is performed using a flexible or a rigid scope. The procedural induced pain is due to navigation through the urethra and from bladder extension due to collection of irrigation fluid. The procedure may be complicated by dysuria, haematuria or symptoms of urinary tract infection.⁵

Despite only taking a few minutes, the procedure can be so uncomfortable that sometimes the patient refuses to proceed or chooses to have a re-scope under local anaesthesia in future. Greenstein *et al.*, (2014) evaluated 1320 patients who underwent diagnostic local cystoscopy and showed a higher pain level following a first-time scope than in a repeated scope, with Visual Analogue Scale (VAS) values of $2.8 \pm 1.6\text{SD}$ vs $2.2 \pm 1.4\text{SD}$ respectively, with a $p\text{-value} < 0.001$.⁶

Initially pain was defined by the International Association for the Study of Pain (IASP) in 1979, as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. This definition was globally accepted and adopted by researchers and the World Health Organization.⁷ However, many criticised this definition because it was not all inclusive and did not describe the brain-body interaction, and it failed to describe the psychological aspect of pain. In 2020 the IASP revised the old definition and released an updated version which now defines pain as an unpleasant sensory and emotional experience associated with, or resembling an association with actual or potential tissue damage.⁷

Pain characteristics depend on stimulus intensity, location, source and quality which are tightly linked to activation of nociceptors and nerves that signal mechanical, thermal or chemical stimuli.^{8, 9} The physiology of pain is a protective mechanism that leads to withdrawal from tissue-damaging stimuli, and inhibiting actions that could further harm already injured areas. This is critically important to make living beings aware of future decisions to avoid and prevent tissue damage.¹⁰

The ability of the brain to modulate pain perception was first observed during the second world war by United States army doctors who were treating soldiers' wounds without analgesia, with no reported pain or only mild pain, despite the severity of the wounds.¹¹ Moreover, these individuals were fully awake and not in shock during the

wound management, which implied that strong emotions may block pain.¹¹ Similarly, some athletes continue competing despite having serious sport injuries, which also indicates the possibility of endogenous or psychological pain modulation.¹² Pain modulation can occur at any level from the brain, brainstem or spinal cord, which is initiated either pharmacologically, motivationally, emotionally or by distraction. Sometimes the exact mechanism of modulation is not clearly understood, for instance in re-appraisal-, control-, and pain coping due to religious beliefs.¹²

Due to its very subjective nature the measurement of pain has been problematic. In 1983 Price *et al.*, validated the use of VAS in pain assessment.¹³ The VAS consists of an uninterrupted horizontal line, typically 10cm in printed length, with two expressive phrases at the two extremities. The scale commonly ranges from 0 (left, least extreme) to 10 (right, most extreme).¹³

There are four types of VAS:

1. The traditional VAS scale, which is a 100mm continuous horizontal line from (0) no pain to (100) worst pain possible.¹⁴
2. A vertical VAS scale, which is a vertical line extending from no pain at the bottom to the worst imaginable pain at the top.¹⁴
3. Typical numeric horizontal pain scale, which is the commonly used 11 point scale from 0 no pain to 10 excruciating pain. Symbols can be added to clarify the score and make it more understandable.¹⁴
4. The Iowa Pain Thermometer employs a vertical format and visual metaphor to indicate the rise or fall in pain intensity in a way similar to how a thermometer registers temperature.¹⁴

There is no consensus on which of the four types is superior to the other, but the Traditional 100mm scale was described first and was widely used. Recently the 11

point scale has been commonly used for its simplicity and the potential to add expression symbols.¹⁴ According to the 11 point scale, severity of pain can be described as mild pain from 1 to 3, moderate pain from 4 to 6 and severe pain from more than 6.¹⁴

Apart from the VAS there are many other ways of measuring pain from using verbal descriptive words as in the McGill pain scale, coin scales representing the amount of money patients would pay for pain relief or face scales such as the Wong-Baker scale. The use of some kind of VAS is most commonly used although it has some limitations – education level and clear explanation.¹⁴

Many studies have been performed to understand the severity of pain during local cystoscopy and aimed to make it more pleasant for the patients: In a prospective multi-institutional study of 300 cystoscopies, 150 were rigid cystoscopies and the other 150 were flexible cystoscopies. The results showed that flexible cystoscopy inflicts less pain in men who had the procedure for the first time, while not influencing the pain sensation in the patients who had the experience previously; hence the type of scope is an independent risk factor for pain perception.¹⁵

The type of lubricant jelly used may also influence pain levels. The usual pain relief used is lidocaine jelly, which requires a delay period after application before the cystoscopy can be performed. Vasudeva *et al.*, (2014) did a prospective randomised study to clarify the optimum intra-urethral dwell time of 2% lidocaine jelly for pain relief during outpatient rigid cystoscopy. Four hundred patients were randomised into four groups (A, B, C, D), correlating with the procedure starting time of 5, 10, 15 or 20 minutes after 2% lidocaine jelly application. The study showed that the optimal time to apply the 20ml of 2% lidocaine jelly is 15 minutes before the procedure.¹⁶

The effectiveness of 2% lignocaine pain relief jelly was compared to aquagel, which is a water-based jelly. The patients were divided into two groups, the first group's cystoscopy started 15 minutes after application of 2% lignocaine jelly while the second group's cystoscopy started directly after aquagel jelly was applied around the scope and in the urethra. In both groups the VAS pain score was 3 or less, and there was no significant difference between the two groups in terms of pain control.¹⁷ Of importance, the lignocaine increased the procedure duration, effort and cost with no beneficial effect.¹⁷

In 2013 a prospective controlled study described the severity of rigid cystoscopy induced pain in comparison the urodynamic test induced pain in women. One hundred and nine women were involved, of which 57 underwent cystoscopy and the others underwent urodynamic tests. The cystoscopy was found to cause more pain (VAS 1.9 $\pm$ 1.8SD) than the urodynamic tests (VAS 1.2 $\pm$ 1.6SD). However, patients anticipated both procedures to be more painful than they actually were, and both groups experienced very little pain. Thus there is quite a large psychological component to the perceived pain in these procedures.¹⁸

In order to try to harness the power of psychology in pain control, the effect of audio-stimulation on the procedural pain and anxiety was also studied. Listening to music was assessed for its impact on anxiety and pain during office based flexible cystoscopy. A total of 137 patients were randomised to either office based flexible cystoscopy with (73) or without (64) music. Music was shown to significantly reduce both pain and anxiety in patients undergoing cystoscopy, as well as the patient's discomfort and dissatisfaction with the procedure.^{19, 20}

Furthermore, researchers also investigated whether the pain due to cystoscopy would be reduced by visual distraction if the patient could watch their own procedure being

performed. Of the two studies available in the literature, one such study showed a 40% reduction in pain, while the second study showed no significant effect on the perception of pain.^{21, 22}

Audiovisual distraction (AVD) combines the benefits of visual distraction with those of auditory distraction in order to improve the pain response. AVD has been tried by several different medical disciplines in other areas. For example, a total of 37 patients participated in a study to demonstrate the effect of audiovisual distraction on the patient's pain perception during aural microsuction. The patients watched their own microsuction procedure of one ear on a television screen, while they did not view the microsuction procedure of the other ear. The mean VAS pain score for the viewed side was 2.43 vs 3.48 on the not-viewed side ($p=0.003$). The effect of audiovisual distraction on pain during aural microsuction thus significantly reduced pain perception during the procedure.²³

Additionally, the effect of passive visual distraction on pain and anxiety was tested on women who had colposcopy procedures at the Brigham- and the Women's Hospital Colposcopy Clinics. In this study, visual distraction by displaying images on a light diffuser installed within the examination room's ceiling light, decreased the perception of pain but it did not affect the patient's anxiety during colposcopy.²⁴

Conversely, audiovisual distraction did not significantly reduce the perceived pain during an endo-venous thermal ablation under tumescent anaesthesia. In this study the patients were randomised into two groups: not distracted (-AVD) and distracted (+AVD). According to the VAS pain score, the distracted group's pain score was 2.6 ($\pm 2.3SD$) vs 2.85 ($\pm 1.7SD$) for the non-distracted group. There was not a statistically significant difference between the two groups ($p=0.68$).²⁵

Gupta *et al.* studied the effect of various methods of distraction on pain and dissatisfaction during out-patient rigid cystoscopy performed under local anaesthetic. The patients were randomised into four groups, each group underwent rigid cystoscopy while either: listening to music (group I), real time visualisation of the procedure (group II), listening to music during real time visualisation of the procedure (group III), or without any distraction (group IV). VAS for group I was $4.08 \pm 1.56SD$, for group II it was $3.46 \pm 1.43SD$, for group III $3.16 \pm 1.25SD$ and for group IV VAS was $7.12 \pm 1.85SD$. It was found that the group of patients who had their procedures done with distractions experienced significantly less pain ($p < 0.001$) and greater satisfaction with the procedure ($p < 0.001$) in comparison to the control group.²⁶

Conversely, a meta-analysis and systemic review of 20 studies on the effect of intervention (audiovisual distraction or relaxation based) on pain and anxiety during local anaesthetic surgery, only 30% of studies verified the positive impact of intervention, while 20% were inconclusive and 50% showed no benefit. Interestingly, the relaxation based interventions were more effective than the audiovisual distraction on pain and anxiety.²⁷

Another research group could not prove the effect of virtual reality intervention on pain and anxiety during flexible office based cystoscopy. They randomised 45 patients into a control (23) and a study group (22) and subsequently concluded that no significant difference was experienced in pain and/or anxiety between the two groups.²⁸

In summary, various methods of distraction showed benefit in improving pain perception during local cystoscopy. Audiovisual distraction found to be superior in many studies which motivated us to test it in our institution and circumstances.

References:

1. Tsuchida S, Sugawara H. A new flexible fibercystoscope for visualization of the bladder neck. *J Urol*. 1973;109:830-831.
2. Clayman RV, Reddy P, Lange PH. Flexible fiberoptic and rigid-rod lens endoscopy of the lower urinary tract: a prospective controlled comparison. *J Urol*. 1984;131:715-716.
3. Walker L, Liston TG, LL-D RW. Does flexible cystoscopy miss more tumours than rod-lens examination? *Br J Urol*. 1993;72:449-450.
4. Yoshimura R, Wada S, Kishimoto T. Why the flexible cystoscope has not yet been widely introduced? A questionnaire to Japanese urologists. *Int J Urol*. 1999;6:549-559; discussion 60-61.
5. Richard SM, John OD, Joshua JM. Cystoscopy. *JAMA* 2017;317(11):1187.
6. Greenstein A, Senderovich S, Mabjeesh NJ. Is Diagnostic Cystoscopy Painful? Analysis of 1,320 Consecutive Procedures. *Int Braz J Urol* 2014; 40(4):533-38
7. Raja SN, Carr DB, Cohen M, Finnerup NB, Flor H, Gibson S, Keefe FJ, Mogil JS, Ringkamp M, Sluka KA, Song XJ, Stevens B, Sullivan MD, Tutelman PR, Ushida T, Vader K. The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. *Pain*. 2020 Sep 1;161(9):1976-1982.
8. Gold, MS & Gebhart, GF. Nociceptor sensitization in pain pathogenesis. *Nat. Med.* 2010; 16(11):1248–1257.
9. Fields, H.L. Pain: an unpleasant topic. *Pain*: 1999; 82:S61–S69.
10. Redgrave P, Gurney K, Reynolds J. What is reinforced by phasic dopamine signals? *Brain Res Rev*. 2008; 58(2):322-39.
11. Beecher HK. Pain in Men Wounded in Battle. *Ann Surg*. 1946;123(1):96-105.
12. Bingel U, Tracey I. Imaging CNS modulation of pain in humans. *Physiology (Bethesda)*. 2008;23:371-380.
13. Yeung AWK, Wong NSM. The Historical Roots of Visual Analog Scale in Psychology as Revealed by Reference Publication Year Spectroscopy. *Front Hum Neurosci*. 2019;13:86.
14. Reed MD, Van Nostran W. Assessing pain intensity with the visual analogue scale: a plea for uniformity. *J Clin Pharmacol*. 2014 Mar;54(3):241-4.

15. Seklehner S, Remzi M, Fajkovic H, Saratlija-Novakovic Z, Skopek M, Resch I, Duvnjak M, Hruby S, Librenjak D, Hübner W, Breinl E, Riedl C, Engelhardt PF. Prospective multi-institutional study analyzing pain perception of flexible and rigid cystoscopy in men. *Urology* 2015; 85(4):737-41.
16. Vasudeva P, Kumar A, Kumar N, Jha SK, Kumar R, Mohanty A, Nanda B, Singh H. Effect of intraurethral dwell time of local anesthetic jelly on pain perception in men undergoing outpatient rigid cystoscopy: a randomized prospective study. *J Endourol*. 2014 Jul;28(7):846-9.
17. Palit V, Ashurst HN, Biyani CS, Elmasray Y, Puri R, Shah T. Is Using Lignocaine Gel prior to Flexible Cystoscopy Justified? *Urol Int* 2003; 71(4):389-92.
18. Yerlikaya G, Laml T, Elenskaia K, Hanzal E, Kölbl H, Umek W. Pain perception during outpatient cystoscopy: a prospective controlled study. *Eur J Obstet Gynecol Reprod Biol* 2014; 173:101–105.
19. Raheem OA, Mirheydar HS, Lee HJ, Patel Nishant D, Godebu E, Sakamoto K. Does Listening to Music During Office-Based Flexible Cystoscopy Decrease Anxiety in Patients, A Prospective Randomized Trial. *J Endourol* 2015; 29(7):791-6.
20. Yeo JK, Cho DY, Oh MM, Park SS, Park MG. Listening to Music During Cystoscopy Decreases Anxiety, Pain, and Dissatisfaction in Patients: A Pilot Randomized Controlled Trial. *J Endourol* 2013; 27(4):459-62.
21. Cornel EB, Oosterwijk E, Kiemeny L A. The effect on pain experienced by male patients of watching their office-based flexible cystoscopy. *BJU International* 2008; 102(10):1445-6.
22. Patel AR, Jones JS, Angie S, Babineau D. Office Based Flexible Cystoscopy May be Less Painful for Men Allowed to View the Procedure. *J Urol* 2007; 177(5):1843-5.
23. Choudhury N, Amer I, Daniels M, Wareing MJ. Audiovisual distraction reduces pain perception during aural microsuction. *Ann R Coll Surg Engl* 2013; 95(1):34-36.
24. Carwile JL, Feldman S, Johnson NR. Use of a Simple Visual Distraction to Reduce Pain and Anxiety in Patients Undergoing Colposcopy. *J Low Genit Tract Dis* 2014; 18(4):317-21.

25. Zandvoort CE, Toonder IM, Stoopendaal IA, Wittens CH. The effect of distraction on pain perception during an endovenous thermal ablation procedure. *Phlebology* 2016; 31(7):463-70.
26. Gupta S, Das SK, Jana D, Pal DK. Distraction during cystoscopy to reduce pain and increase satisfaction: Randomized control study between real-time visualization versus listening to music versus combined music and real-time visualization. *Urol Ann.* 2019;11(1):33-38.
27. Hudson BF, Ogden J. Exploring the Impact of Intraoperative Interventions for Pain and Anxiety Management During Local Anesthetic Surgery. -A Systematic Review and Meta-Analysis. *J Perianesth Nurs.* 2016 Apr;31(2):118-33.
28. Walker MR, Kallingal GJ, Musser JE, Folen R, Stetz MC, Clark JY. Treatment efficacy of virtual reality distraction in the reduction of pain and anxiety during cystoscopy. *Mil Med.* 2014 Aug;179(8):891-6.

Chapter 2: Instructions to the Authors – Urology Annals

Instructions to the Authors

[About Journal](#) | [Scope Of the Journal](#) | [The Editorial Process](#) | [Clinical trial registry](#) | [Authorship Criteria](#) | [Contribution Details](#) | [Conflicts of Interest](#) | [Submission of the Manuscripts](#) | [Preparation of the Manuscript](#) | [Copies of any permission\(s\)](#) | [Types of Manuscripts](#) | [Sending a revised manuscript](#) | [Reprints](#) | [Manuscript submission, processing and publication charges](#) | [Copyrights](#) | [Checklist](#) | [Contributors' form](#)

✓ About Journal

Urology Annals is a peer-reviewed international journal, published under the auspices of the Saudi Urological Association. The journal's full text is available online at www.urologyannals.com. The journal allows free access (Open Access) to its contents and permits authors to self-archive final accepted version of the articles on any OAI-compliant institutional / subject-based repository.

✓ Scope of the journal

The journal will cover technical, clinical and bioengineering studies related to urology in human well being including ethical and social issues. Articles with clinical interest and implications will be given preference.

✓ The Editorial Process

A manuscript will be reviewed for possible publication with the understanding that it is being submitted to UROLOGY ANNALS alone at that point in time and has not been published anywhere, simultaneously submitted, or already accepted for publication elsewhere. The journal expects that authors would authorize one of them to correspond with the Journal for all matters related to the manuscript. All manuscripts received are duly acknowledged. On submission, editors review all submitted manuscripts initially for suitability for formal review. Manuscripts with insufficient originality, serious scientific or technical flaws, or lack of a significant message are rejected before proceeding for formal peer-review. Manuscripts that are unlikely to be of interest to the UROLOGY ANNALS readers are also liable to be rejected at this stage itself.

Manuscripts that are found suitable for publication in UROLOGY ANNALS are sent to two or more expert reviewers. During submission, the contributor is requested to provide names of two or three qualified reviewers who have had experience in the subject of the submitted manuscript, but this is not mandatory. The reviewers should not be affiliated with the same institutes as the contributor/s. However, the selection of these reviewers is at the sole discretion of the editor. The journal follows a double-blind review process, wherein the reviewers and authors are unaware of each other's identity. Every manuscript is also assigned to a member of the editorial team, who based on the comments from the reviewers takes a final decision on the manuscript. The comments and suggestions (acceptance/ rejection/ amendments in manuscript) received from reviewers are conveyed to the corresponding author. If required, the author is requested to provide a point by point response to reviewers' comments and submit a revised version of the manuscript. This process is repeated till reviewers and editors are satisfied with the manuscript.

Manuscripts accepted for publication are copy edited for grammar, punctuation, print style, and format. Page proofs are sent to the corresponding author. The corresponding author is expected to return the corrected proofs within three days. It may not be possible to incorporate corrections received after that period. The whole process of submission of the manuscript to final decision and sending and receiving proofs is completed online. To achieve faster and greater dissemination of knowledge and information, the journal publishes articles online as 'Ahead of Print' immediately on acceptance.

✓ Clinical trial registry

UROLOGY ANNALS would publish clinical trials that have been registered with a clinical trial registry that allows free online access to public. Registration in the following trial registers is acceptable: <http://www.ctri.in/>; <http://www.actr.org.au/>; <http://www.clinicaltrials.gov/>; <http://isrctn.org/>; <http://www.trialregister.nl/trialreg/index.asp>; and <http://www.umin.ac.jp/ctr>. This is applicable to clinical trials that have begun enrollment of subjects in or after June 2008. Clinical trials that have commenced enrollment of subjects prior to June 2008 would be considered for publication in UROLOGY ANNALS only if they have been registered retrospectively with clinical trial registry that allows unhindered online access to public without charging any fees.

✓ Authorship Criteria

Authorship credit should be based only on substantial contributions to each of the three components mentioned below:

1. Concept and design of study or acquisition of data or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Each contributor should have participated sufficiently in the work to take public responsibility for appropriate portions of the content of the manuscript. The order of naming the contributors should be based on the relative contribution of the contributor towards the study and writing the manuscript. Once submitted the order cannot be changed without written consent of all the contributors. The journal prescribes a maximum number of authors for manuscripts depending upon the type of manuscript, its scope and number of institutions involved (vide infra). The authors should provide a justification, if the number of authors exceeds these limits.

✓ Contribution Details

Contributors should provide a description of contributions made by each of them towards the manuscript. Description should be divided in following categories, as applicable: concept, design, definition of intellectual content, literature search, clinical studies, experimental studies, data acquisition, data analysis, statistical analysis, manuscript preparation, manuscript editing and manuscript review. One or more author should take responsibility for the integrity of the work as a whole from inception to published article and should be designated as 'guarantor'.

✓ Conflicts of Interest / Competing Interests

All authors of must disclose any and all conflicts of interest they may have with publication of the manuscript or an institution or product that is mentioned in the manuscript and/or is important to the outcome of the study presented. Authors should also disclose conflict of interest with products that compete with those mentioned in their manuscript.

✓ Submission of the Manuscripts

All manuscripts must be submitted on-line through the website www.journalonweb.com/ua. First time users will have to register at this site. Registration is free but mandatory. Registered authors can keep track of their articles after logging into the site using their user name and password. If you experience any problems, please contact the editorial office by e-mail at editor@urologyannals.com.

The submitted manuscripts that are not as per the 'Instructions to Authors' would be returned to the authors for technical correction, before they undergo editorial/peer-review. Generally, the manuscript should be submitted in the form of four separate files:

Title Page/First Page File/covering letter:

This file should provide

- a. The type of manuscript (original article, case report, review article, Ethics Forum, Education Forum, Letter to editor, Images, etc.) title of the manuscript, running title, names of all authors/ contributors (with their highest academic degrees, designation and affiliations) and name(s) of department(s) and/ or institution(s) to which the work should be credited, . All information which can reveal your identity should be here. Use text/rtf/doc files. Do not zip the files.
- b. The total number of pages, total number of photographs and word counts separately for abstract and for the text (excluding the references, tables and abstract), word counts for introduction + discussion in case of an original article;
- c. Source(s) of support in the form of grants, equipment, drugs, or all of these;
- d. Acknowledgement, if any. One or more statements should specify 1) contributions that need acknowledging but do not justify authorship, such as general support by a departmental chair; 2) acknowledgments of technical help; and 3) acknowledgments of financial and material support, which should specify the nature of the support. This should be included in the title page of the manuscript and not in the main article file.
- e. If the manuscript was presented as part at a meeting, the organization, place, and exact date on which it was read. A full statement to the editor about all submissions and previous reports that might be regarded as redundant publication of the same or very similar work. Any such work should be referred to specifically, and referenced in the new paper. Copies of such material should be included with the submitted paper, to help the editor decide how to handle the matter.
- f. Registration number in case of a clinical trial and where it is registered (name of the registry and its URL)

- g. Conflicts of interest of each author/ contributor. A statement of financial or other relationships that might lead to a conflict of interest, if that information is not included in the manuscript itself or in an authors' form
- h. Criteria for inclusion in the authors'/ contributors' list
- i. A statement that the manuscript has been read and approved by all the authors, that the requirements for authorship as stated earlier in this document have been met, and that each author believes that the manuscript represents honest work, if that information is not provided in another form (see below); and
- j. The name, address, e-mail, and telephone number of the corresponding author, who is responsible for communicating with the other authors about revisions and final approval of the proofs, if that information is not included on the manuscript itself.

Blinded Article file:

The manuscript must not contain any mention of the authors' names or initials or the institution at which the study was done or acknowledgements. Page headers/running title can include the title but not the authors' names. Manuscripts not in compliance with The Journal's blinding policy will be returned to the corresponding author. The main text of the article, beginning from Abstract till References (including tables) should be in this file. Use rtf/doc files. Do not zip the files. Limit the file size to 1024 kb (1 MB). Do not incorporate images in the file. The pages should be numbered consecutively, beginning with the first page of the blinded article file.

Images:

Submit good quality color images. Each image should be less than 4 MB in size. Size of the image can be reduced by decreasing the actual height and width of the images (keep up to 1800 x 1200 pixels or 5-6 inches). Images can be submitted as jpeg files. Do not zip the files. Legends for the figures/images should be included at the end of the article file.

The contributors' / copyright transfer form

(template provided below) has to be submitted in original with the signatures of all the contributors within two weeks of submission via courier, fax or email (copyright AT medknow DOT com) as a scanned image. High resolution images (up to 5 MB each) can be sent by email on images AT medknow DOT com).

The hard copies of the Contributors' form / copyright transfer form may be sent to the following addresses or submitted online from the authors' area on www.journalonweb.com/ua.

UROLOGY ANNALS

c/o Dr. Khalid Fouda Neel
Dept of Surgery (37)
King Khalid University Hospital and
College of Medicine
P. O. Box 2925
Riyadh 11461, Saudi Arabia

✓ Preparation of the Manuscript

Manuscripts must be prepared in accordance with "Uniform requirements for Manuscripts submitted to Biomedical Journals" developed by the International Committee of Medical Journal Editors (October 2006). The uniform requirements and specific requirement of **UROLOGY ANNALS** are summarized below. Before submitting a manuscript, contributors are requested to check for the latest instructions available. Instructions are also available from the website of the journal (www.urologyannals.com) and from the manuscript submission site (<http://www.journalonweb.com/ua>).

UROLOGY ANNALS accepts manuscripts written in American English.

✓ Copies of any permission(s)

To reproduce published material, and to use illustrations or report information about identifiable people a copy of the permission obtained must accompany the manuscript. Copies of any and all published articles or other manuscripts in preparation or submitted elsewhere that are related to the manuscript must also accompany the manuscript. These copies should be sent to UROLOGY ANNALS c/o Dr. Khalid Fouda Neel, Dept of Surgery (37), King Khalid University Hospital and, College of Medicine, P. O. Box 2925, Riyadh 11461, Saudi Arabia.

✓ Types of Manuscripts

Original articles:

These include randomized controlled trials, intervention studies, studies of screening and diagnostic test, outcome studies, cost effectiveness analyses, case-control series, and surveys with high response rate. The text of original articles amounting to up to 3000 words (excluding Abstract, references and Tables) should be divided into sections with the headings Abstract, Key-words, Introduction, Material and Methods, Results, Discussion, References, Tables and Figure legends.

Introduction: State the purpose and summarize the rationale for the study or observation.

Materials and Methods: It should include and describe the following aspects:

Ethics:

When reporting studies on human beings, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 2000 (available at http://www.wma.net/e/policy/17-c_e.html). For prospective studies involving human participants, authors are expected to mention about approval of (regional/ national/ institutional or independent Ethics Committee or Review Board, obtaining informed consent from adult research participants and obtaining assent for children aged over 7 years participating in the trial. The age beyond which assent would be required could vary as per regional and/ or national guidelines. Ensure confidentiality of subjects by desisting from mentioning participants' names, initials or hospital numbers, especially in illustrative material. When reporting experiments on animals, indicate whether the institution's or a national research council's guide for, or any national law on the care and use of laboratory animals was followed.

Evidence for approval by a local Ethics Committee (for both human as well as animal studies) must be supplied by the authors on demand. Animal experimental procedures should be as humane as possible and the details of anesthetics and analgesics used should be clearly stated. The ethical standards of experiments must be in accordance with the guidelines provided by the CPCSEA and World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Humans for studies involving experimental animals and human beings, respectively). The journal will not consider any paper which is ethically unacceptable. A statement on ethics committee permission and ethical practices must be included in all research articles under the 'Materials and Methods' section.

Study design:

Selection and Description of Participants: Describe your selection of the observational or experimental participants (patients or laboratory animals, including controls) clearly, including eligibility and exclusion criteria and a description of the source population. **Technical information:** Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods (see below); provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Reports of randomized clinical trials should present information on all major study elements, including the protocol, assignment of interventions (methods of randomization, concealment of allocation to treatment groups), and the method of masking (blinding), based on the CONSORT Statement (<http://www.consort-statement.org>).

Reporting Guidelines for Specific Study Designs

Initiative	Type of study	Source
CONSORT	randomized controlled trials	http://www.consort-statement.org
STARD	studies of diagnostic accuracy	http://www.consort-statement.org/stardstatement.htm
QUOROM	systematic reviews and meta-analyses	http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf
STROBE	observational studies in epidemiology	http://www.strobe-statement.org
MOOSE	meta-analyses of observational studies in epidemiology	http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf

Statistics: Whenever possible quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Authors

should report losses to observation (such as, dropouts from a clinical trial). When data are summarized in the Results section, specify the statistical methods used to analyze them. Avoid non-technical uses of technical terms in statistics, such as 'random' (which implies a randomizing device), 'normal', 'significant', 'correlations', and 'sample'. Define statistical terms, abbreviations, and most symbols. Specify the computer software used. Use upper italics (*P* 0.048). For all *P* values include the exact value and not less than 0.05 or 0.001. Mean differences in continuous variables, proportions in categorical variables and relative risks including odds ratios and hazard ratios should be accompanied by their confidence intervals.

Results: Present your results in a logical sequence in the text, tables, and illustrations, giving the main or most important findings first. Do not repeat in the text all the data in the tables or illustrations; emphasize or summarize only important observations. Extra- or supplementary materials and technical detail can be placed in an appendix where it will be accessible but will not interrupt the flow of the text; alternatively, it can be published only in the electronic version of the journal.

When data are summarized in the Results section, give numeric results not only as derivatives (for example, percentages) but also as the absolute numbers from which the derivatives were calculated, and specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Where scientifically appropriate, analyses of the data by variables such as age and sex should be included.

Discussion: Include summary of *key findings* (primary outcome measures, secondary outcome measures, results as they relate to a prior hypothesis); *Strengths and limitations* of the study (study question, study design, data collection, analysis and interpretation); *Interpretation and implications* in the context of the totality of evidence (is there a systematic review to refer to, if not, could one be reasonably done here and now?, what this study adds to the available evidence, effects on patient care and health policy, possible mechanisms); *Controversies* raised by this study; and *Future research directions* (for this particular research collaboration, underlying mechanisms, clinical research).

Do not repeat in detail data or other material given in the Introduction or the Results section. In particular, contributors should avoid making statements on economic benefits and costs unless their manuscript includes economic data and analyses. Avoid claiming priority and alluding to work that has not been completed. New hypotheses may be stated if needed, however they should be clearly labeled as such. About 30 references can be included. These articles generally should not have more than six authors.

Review Articles:

It is expected that these articles would be written by individuals who have done substantial work on the subject or are considered experts in the field. A short summary of the work done by the contributor(s) in the field of review should accompany the manuscript.

The prescribed word count is up to 3000 words excluding tables, references and abstract. The manuscript may have about 90 references. The manuscript should have an unstructured Abstract (250 words) representing an accurate summary of the article. The section titles would depend upon the topic reviewed. Authors submitting review article should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract.

The journal expects the contributors to give post-publication updates on the subject of review. The update should be brief, covering the advances in the field after the publication of the article and should be sent as a letter to editor, as and when major development occurs in the field.

Case reports:

New, interesting and rare cases can be reported. They should be unique, describing a great diagnostic or therapeutic challenge and providing a learning point for the readers. Cases with clinical significance or implications will be given priority. These communications could be of up to 1000 words (excluding Abstract and references) and should have the following headings: Abstract (unstructured), Key-words, Introduction, Case report, Discussion, Reference, Tables and Legends in that order.

The manuscript could be of up to 1000 words (excluding references and abstract) and could be supported with up to 10 references. Case Reports could be authored by up to four authors.

Letter to the Editor:

These should be short and decisive observations. They should preferably be related to articles previously published in the Journal or views expressed in the journal. They should not be preliminary observations that need a later paper for validation. The letter could have up to 500 words and 5 references. It could be generally authored by not more than four authors.

Other:

Editorial, Guest Editorial, and Commentary are solicited by the editorial board.

References

References should be *numbered* consecutively in the order in which they are first mentioned in the text (not in alphabetic order). *Identify references in text*, tables, and legends by Arabic numerals in superscript with square bracket after the punctuation marks. *References cited only* in tables or figure legends should be numbered in accordance with the sequence established by the first identification in the text of the particular table or figure. Use the style of the examples below, which are based on the formats used by the NLM in *Index Medicus*. The titles of journals *should be abbreviated* according to the style used in *Index Medicus*. Use complete name of the journal for non-indexed journals. Avoid using abstracts as references. Information from manuscripts submitted but not accepted should be cited in the text as "unpublished observations" with written permission from the source. Avoid citing a "personal communication" unless it provides essential information not available from a public source, in which case the name of the person and date of communication should be cited in parentheses in the text.

The commonly cited types of references are shown here, for other types of references such as newspaper items please refer to ICMJE Guidelines (<http://www.icmje.org> or http://www.nlm.nih.gov/bsd/uniform_requirements.html).

Download a [PowerPoint presentation](#) on common reference styles and using the reference checking facility on the manuscript submission site.

Articles in Journals

- Standard journal article (for up to six authors): Shukla N, Husain N, Agarwal GG, Husain M. Utility of cysticercus fasciolaris antigen in Dot ELISA for the diagnosis of neurocysticercosis. *Indian J Med Sci* 2008;62:222-7.
- Standard journal article (for more than six authors): List the first six contributors followed by *et al*.

Nozari Y, Hashemlu A, Hatmi ZN, Sheikhatvan M, Irvani A, Bazdar A, *et al*. Outcome of coronary artery bypass grafting in patients without major risk factors and patients with at least one major risk factor for coronary artery disease. *Indian J Med Sci* 2007;61:547-54

- Volume with supplement: Shen HM, Zhang QF. Risk assessment of nickel carcinogenicity and occupational lung cancer. *Environ Health Perspect* 1994; 102 Suppl 1:275-82.
- Issue with supplement: Payne DK, Sullivan MD, Massie MJ. Women's psychological reactions to breast cancer. *Semin Oncol* 1996; 23(1, Suppl 2):89-97.

Books and Other Monographs

- Personal author(s): Ringsven MK, Bond D. Gerontology and leadership skills for nurses. 2nd ed. Albany (NY): Delmar Publishers; 1996.
- Editor(s), compiler(s) as author: Norman IJ, Redfern SJ, editors. Mental health care for elderly people. New York: Churchill Livingstone; 1996.
- Chapter in a book: Phillips SJ, Whisnant JP. Hypertension and stroke. In: Laragh JH, Brenner BM, editors. Hypertension: pathophysiology, diagnosis, and management. 2nd ed. New York: Raven Press; 1995. pp. 465-78.

Electronic Sources as reference

Journal article on the Internet

Aboud S. Quality improvement initiative in nursing homes: the ANA acts in an advisory role. *Am J Nurs* [serial on the Internet]. 2002 Jun [cited 2002 Aug 12];102(6):[about 3 p.]. Available from: <http://www.nursingworld.org/AJN/2002/june/Wawatch.htm>

Monograph on the Internet

Foley KM, Gelband H, editors. Improving palliative care for cancer [monograph on the Internet]. Washington: National Academy Press; 2001 [cited 2002 Jul 9]. Available from: <http://www.nap.edu/books/0309074029/html/>.

Homepage/Web site

Cancer-Pain.org [homepage on the Internet]. New York: Association of Cancer Online Resources, Inc.; c2000-01 [updated 2002 May 16; cited 2002 Jul 9]. Available from: <http://www.cancer-pain.org/>.

Part of a homepage/Web site

American Medical Association [homepage on the Internet]. Chicago: The Association; c1995-2002 [updated 2001 Aug 23; cited 2002 Aug 12]. AMA Office of Group Practice Liaison; [about 2 screens]. Available from: <http://www.ama-assn.org/ama/pub/category/1736.html>

Tables

- Tables should be self-explanatory and should not duplicate textual material.
- Tables with more than 10 columns and 25 rows are not acceptable.
- Number tables, in Arabic numerals, consecutively in the order of their first citation in the text and supply a brief title for each.
- Place explanatory matter in footnotes, not in the heading.
- Explain in footnotes all non-standard abbreviations that are used in each table.
- Obtain permission for all fully borrowed, adapted, and modified tables and provide a credit line in the footnote.
- For footnotes use the following symbols, in this sequence: *, †, ‡, §, ||, ¶, **, ††, ‡‡, §§, ¶¶
- Tables with their legends should be provided at the end of the text after the references. The tables along with their number should be cited at the relevant place in the text

Illustrations (Figures)

- Upload the images in JPEG format. The file size should be within 4 MB in size while uploading.
- Figures should be numbered consecutively according to the order in which they have been first cited in the text.
- Labels, numbers, and symbols should be clear and of uniform size. The lettering for figures should be large enough to be legible after reduction to fit the width of a printed column.
- Symbols, arrows, or letters used in photomicrographs should contrast with the background and should be marked neatly with transfer type or by tissue overlay and not by pen.
- Titles and detailed explanations belong in the legends for illustrations not on the illustrations themselves.
- When graphs, scatter-grams or histograms are submitted the numerical data on which they are based should also be supplied.
- The photographs and figures should be trimmed to remove all the unwanted areas.
- If photographs of individuals are used, their pictures must be accompanied by written permission to use the photograph.
- If a figure has been published elsewhere, acknowledge the original source and submit written permission from the copyright holder to reproduce the material. A credit line should appear in the legend for such figures.
- Legends for illustrations: Type or print out legends (maximum 40 words, excluding the credit line) for illustrations using double spacing, with Arabic numerals corresponding to the illustrations. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, identify and explain each one in the legend. Explain the internal scale (magnification) and identify the method of staining in photomicrographs.
- Final figures for print production: If the uploaded images are not printable quality, the publisher office may request for higher resolution images which can be sent at the time of acceptance of the manuscript. Send sharp, glossy, un-mounted, color photographic prints, with height of 4 inches and width of 6 inches at the time of submitting the revised manuscript. Print outs of digital photographs are not acceptable. If digital images are the only source of images, ensure that the image has minimum resolution of 300 dpi or 1800 x 1600 pixels in TIFF format. Send the images on a CD. Each figure should have a label pasted (avoid use of liquid gum for pasting) on its back indicating the number of the figure, the running title, top of the figure and the legends of the figure. Do not write the contributor/s' name/s. Do not write on the back of figures, scratch, or mark them by using paper clips.
- The Journal reserves the right to crop, rotate, reduce, or enlarge the photographs to an acceptable size.

Protection of Patients' Rights to Privacy

Identifying information should not be published in written descriptions, photographs, sonograms, CT scans, etc., and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian, wherever applicable) gives informed consent for publication. Authors should remove patients' names from figures unless they have obtained informed consent from the patients. The journal abides by ICMJE guidelines:

- 1) Authors, not the journals nor the publisher, need to obtain the patient consent form before the publication and have the form properly archived. The consent forms are not to be uploaded with the cover letter or sent through email to editorial or publisher offices.
- 2) If the manuscript contains patient images that preclude anonymity, or a description that has obvious indication to the identity of the patient, a statement about obtaining informed patient consent should be indicated in the manuscript.

✓ Sending a revised manuscript

The revised version of the manuscript should be submitted online in a manner similar to that used for submission of the manuscript for the first time. However, there is no need to submit the 'First Page' or 'Covering Letter' file while submitting a revised version. When submitting a revised manuscript, contributors are requested to include, the 'referees' remarks along with point to point clarification at the beginning in the revised file itself. In addition, they are expected to mark the changes as underlined or colored text in the article.

✓ Reprints and proofs

Journal provides no free printed reprints. Authors can purchase reprints, payment for which should be done at the time of submitting the proofs.

Proofs will be sent to the corresponding authors by email approximately 2 weeks before the publication date. The issues are published in last week of the previous month.

✓ Manuscript submission, processing and publication charges

Submission charge:

Journal charges following fee on submission

Case Report, Letter to the Editor, Original Article, Review: US \$ 20

Article processing charge:

The journal charges following fee on acceptance

Case Report, Letter to the Editor: US \$ 80 (for overseas authors), INR 4800 (for authors from India)

Original Article, Review: US \$ 100 (for overseas authors), INR 6000 (for authors from India)

(As mandated by the Indian Government and based on the GST Law and procedures, Wolters Kluwer India Private Ltd, would be charging GST @18% on fees collected from Indian authors with effect from 1st July 2017. The said tax will be in addition to the prices maintained on the website to be collected from the authors and will be paid to the Indian Government..)

✓ Copyrights

The entire contents of the Urology Annals are protected under Indian and international copyrights. The Journal, however, grants to all users a free, irrevocable, worldwide, perpetual right of access to, and a license to copy, use, distribute, perform and display the work publicly and to make and distribute derivative works in any digital medium for any reasonable non-commercial purpose, subject to proper attribution of authorship and ownership of the rights. The journal also grants the right to make small numbers of printed copies for their personal non-commercial use under Creative Commons Attribution-Noncommercial-Share Alike 3.0 Unported License.

✓ Checklist

Covering letter

- Signed by all contributors
- Previous publication / presentations mentioned
- Source of funding mentioned
- Conflicts of interest disclosed

Authors

- Middle name initials provided
- Author for correspondence, with e-mail address provided
- Number of contributors restricted as per the instructions
- Identity not revealed in paper except title page (e.g. name of the institute in Methods, citing previous study as 'our study', names on figure labels, name of institute in photographs, etc.)

Presentation and format

- Double spacing
- Margins 2.5 cm from all four sides

- Title page contains all the desired information
- Running title provided (not more than 50 characters)
- Abstract page contains the full title of the manuscript
- Abstract provided (about 150 words for case reports and 250 words for original articles)
- Structured abstract provided for an original article
- Key words provided (three or more)
- Introduction of 75-100 words
- Headings in title case (not ALL CAPITALS)
- The references cited in the text should be after punctuation marks, in superscript with square bracket.
- References according to the journal's instructions, punctuation marks checked
- Send the final article file without 'Track Changes'

Language and grammar

- Uniformly American English
- Write the full term for each abbreviation at its first use in the title, abstract, keywords and text separately unless it is a standard unit of measure. Numerals from 1 to 10 spell out
 - Numerals at the beginning of the sentence spell out
 - Check the manuscript for spelling, grammar and punctuation errors
 - If a brand name is cited, supply the manufacturer's name and address (city and state/country).
 - Species names should be in italics

Tables and figures

- No repetition of data in tables and graphs and in text
- Actual numbers from which graphs drawn, provided
- Figures necessary and of good quality (colour)
- Table and figure numbers in Arabic letters (not Roman)
- Labels pasted on back of the photographs (no names written)
- Figure legends provided (not more than 40 words)
- Patients' privacy maintained (if not permission taken)
- Credit note for borrowed figures/tables provided
- Write the full term for each abbreviation used in the table as a footnote

✓ Contributors' form

[Click here to download copyright form](#)

Chapter 3: Urology Annals manuscript:

3.1 Cover page

Type of article: Original article

Title: Pain modulation by audiovisual distraction during local cystoscopy

Authors: Amadadin Alhlib MBBS¹, Mohamed Haffejee FCS (Urology)¹, Marietha Nel PhD²

¹ Division of Urology, ² Department of Surgery, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

Abstract: Page - 1, total page word count – 242

Manuscript: Pages– 7½, word count – 2170

Introduction: Pages – 1, word count – 250

Discussion: Pages – 2, word count – 537

Photographs: None

Sources of support: None

Date: 23 June 2021

3.2. Manuscript:

Abstract:

Introduction: Cystoscopy is one of the most common urological procedures used for either diagnostics, therapeutics or for surveillance. It may be performed under local- or general anaesthesia because the procedure is associated with pain and discomfort.

Aims: The aim of the study was to compare the levels of perceived pain during local cystoscopy with and without audiovisual distraction (AVD).

Methods: A randomized control study was performed at the local cystoscopy theatre of the Urology Division at Charlotte Maxeke Johannesburg academic hospital.

Approximately half the patients already booked for the local rigid cystoscopy procedure were exposed to a distracting musical video during the procedure (study group) while the control group was not. Pain levels were measured using a numerical visual analogue scale.

Results: A total of 91 patients participated in the study with 48 patients in the study group and 43 patients in the control group. The Visual Analogue Scale (VAS) ranged between 1-5/10 in the study group and 1-8/10 in the control group. The mean VAS was ($2.52 \pm 1.2SD$) in the study group and ($4.97 \pm 1.35SD$) in the control group ($P < 0.001$).

Conclusion: Audiovisual distraction during local rigid cystoscopy is highly recommended and advised to be more widely used as a routine measure to reduce cystoscopy induced pain.

Key words: cystoscopy, audiovisual distraction, cystoscopy induced pain

Running title: Audiovisual distraction during cystoscopy

Key messages: AVD is recommended during cystoscopy under local anaesthesia since it improves the patient's perception of procedure induced pain.
--

Introduction

Cystoscopy is a common procedure in urology. It is a safe procedure to evaluate the lower urinary tract disorders like voiding dysfunction, hematuria and anatomical abnormalities, but it is fairly painful for the patients and is often preceded by a feeling of fear and anxiety. For that reason, methods to reduce pain and anxiety in patients who undergo rigid cystoscopy is essential.

There are two types of cystoscopy, rigid and flexible.¹ Cystoscopy is associated with pain¹ especially in first-time patients who experience more pain than those having a repeat scope ($P < 0.001$).² Although flexible cystoscopy is less traumatic than rigid cystoscopy and inflicts less pain than rigid scoping on first-time scoped men, it did not cause less pain in patients who had the procedure previously.³

Various methods, pharmacological and non-pharmacological are used to decrease pain during the procedure. Types of distraction to aid in pain relief during cystoscopy procedures are however controversial. In one study where patients watched their own procedure, there was a 40% pain reduction,⁴ while another similar study showed no effect.⁵ that music-, video- or stress ball distractions decreased pain during rigid cystoscopy,⁶ and audio-stimulation reduced pain during flexible cystoscopy.⁷

To our knowledge there is no published South African study on testing the effect of audiovisual distraction on pain during cystoscopy. The aim of this current study was to compare the levels of perceived pain during local rigid cystoscopy with and without audiovisual distraction and to establish the effectiveness of audiovisual distraction on cystoscopy induced pain.

Materials and methods

Sample population:

Almost all of the patients had already been booked for local rigid cystoscopy before the study started at our urology out patients' clinic for the period between the 1st of July 2019 and the 1st of December 2019. All patients were counseled before the procedure, given an information sheet and asked to sign an informed consent form should they be willing to participate in the study. All adult male patients who gave consent to participate in the study were included.

Procedure:

The effect of audiovisual distraction on pain during rigid local cystoscopy was determined according to the 11-point VAS pain levels score from 0 (no pain) to 10 (excruciating pain). The pain levels for both the study and the control group were presented by facial expression symbols in the patient questionnaire. A questionnaire was designed for the patients to describe their experience during the procedure, in addition to comments on their previous local cystoscopy experience if there was any. Each patient was given an individual study number by the principal investigator (PI). The simple randomization technique was used,⁸ each patient chose a folded piece of white paper from a jar containing 150 pieces of paper, with either the letter C or S written on it in order to allocate the patients to either the control group (C) or the study group (S). Patients were thus randomly distributed into two groups: the first group (C) had the procedure done under the current conditions without AVD (control group) and the second group (S) watched a video clip with music (time lapse with sunsets, clouds and stars) on a tablet during the procedure (test group). The video was of 20 minutes duration, showing sunset scenes with relaxing background music. All study group patients watched the same video and no patient's procedure took

longer than the duration of the video. The study group watched the video throughout the entire procedure.

The routine procedure was as follows: patients were placed in the lithotomy position, and the genitalia and the perineum were cleaned with savlon solution if they were not allergic to it. Otherwise, either betadine or normal saline was used. The procedure commenced 15 minutes after applying 20ml 2% remicaine jelly in the urethra of control- and study patients. The procedures were all performed with a Size 19 French cystoscopy rigid metal sheet covering a 30 degree camera lens which is connected to a display screen. The scope was also connected to a sterile one liter bag of normal saline used for irrigation, while avoiding intentional bladder over-distension. The bladder was emptied at the end of the procedure and an oral analgesic (Painblok tablets. GDC. Gulf Drug Company, 22 Burnside Drive, Old Mill Industrial Park, Mount Edgecombe, 4300, South Africa, info@gulfdrug.co.za) was prescribed if the patient complained of pain.

On average the procedure duration was approximately 5 minutes, within a range of 3 to 8 minutes. The cystoscopy procedures were all done by the PI. All patients had a detailed explanation by the operating team before the start of the procedure, on how to complete the questionnaire. Approximately 15 minutes after the procedure and once the patient was dressed, the questionnaire including the attached VAS was filled in in a private room. Both groups described the pain perceived during the procedure according to the patient questionnaire and the VAS score.

Ethics:

Signed permission was obtained from the Urology Department head as well as from the Charlotte Maxeke Johannesburg Academic Hospital chief executive officer

before we applied for Ethics approval. The study only commenced after approval for the study was obtained from the Human Research Ethics Committee (medical) of the Faculty of Health Sciences at the University of the Witwatersrand with certificate number: M180817 (**Appendix V**).

Data analysis:

The collected questionnaire data was entered into a Microsoft Excel spread sheet. The STATA Version 14.2 (College Station, TX, USA) statistical software package was used to analyze the data. Statistics for categorical data were described using percentages and means and standard deviations for normally distributed data with medians and ranges used for skewed or non-parametric data. The pain levels between the two groups were compared using the Mann Whitney U test for non-parametric data. A p-value of <0.05 was considered statistically significant.

Results

A total of 117 patients consented to participate in the study, although 12 were excluded because of obvious neurological conditions. Another 14 patients' (eight from the control group and six from the study group) data was excluded from the data collection sheet and statistical analysis, because of other surgical interventions performed on them. As per the exclusion criteria of this current study, of the 14 patients, nine patients were excluded because of having a direct Vision Internal Urethrotomy, and five patients were excluded because a biopsy was taken from their urinary bladder during the cystoscopy. Thus, a total of 91 patients' data were collected for data analysis, with 43 patients in the control group and 48 in the study group.

All patients were adult males with a mean age of 66.6 years (± 10.43 SD) for the study group and 65.79 years (± 13.79 SD) for the control group ($P=0.36$). The ages below

60 or above 60 years were not considered an important factor in either of the two groups. In the study group the mean VAS for ages below 60 years was 2.54 (± 1.3 SD), whereas for those above 60 years, the VAS was 2.51 (± 1.16 SD). In the control group, the mean VAS for ages below 60 years was 5.1 (± 0.99 SD) and for ages above 60 years the VAS was 4.91 (± 1.44 SD). This again was indeed found not statistically significant in comparison to pain levels according to VAS ($P=0.17$) for the study group and ($P=0.39$) for the control group.

A total of 16 (17.6%) patients (nine men from the control group and seven men from the study group) had been scoped before the study and attended the clinic for a follow-up cystoscopy (Figure 1). The mean VAS pain score for the patients in the study group who had previously been scoped was 2.6 (± 1.32 SD), while it was 2.4 (± 1.18 SD) for patients never scoped before ($P=0.35$). On the contrary, in the control group the previously scoped patients had a VAS pain score of 4.42 (± 1.27 SD), opposed to a VAS pain score of 5.08 (± 1.38 SD) in patients who had cystoscopy for the very first time ($P=0.14$). Overall, the mean VAS scores for the whole study group (previously scoped or not) ranged between 1-5/10 with a mean of 2.52 (± 1.2 SD) and for the whole control group (previously scoped or not) VAS was between 1-8/10 with a mean of 4.97 (± 1.35 SD). The AVD intervention patients had significantly lower pain scores compared to the control group ($P =0.001$) (Table1).

Some patients complained of continuous pain as an early complication after the cystoscopy procedure. Twenty three patients, 12 patients in the control group and 11 in the study group, suffered from pain right after the procedure. Ten patients had urethral bleeding, four in the control group and six in the study group. Only one patient had both pain and urethral bleeding immediately after the procedure (Figure 2).

Discussion

In the 91 patients who took part in the study there was no difference in pain levels related to ages less than or more than 60 years. There was a significant difference in pain levels between those patients who had the audiovisual distraction compared to the control group whether previously scoped ($P=0.008$) or not ($P<0.001$). There was no difference in pain levels within the groups between previously scoped and first time scopes, with $P=0.35$ for the study group and $P=0.14$ for the control group.

All patients who come for a local cystoscopy generally ask how painful the procedure is, whether they will be able to tolerate the pain and what they should do to relief the pain. Pain is defined as an unpleasant sensory and emotional experience associated with, or resembling an association with actual or potential tissue damage (IASP 2020).⁹

In 1983 Price *et al.*, validated the use of VAS in pain assessment.¹⁰ Eleven points on the VAS scale (from 0 to 10) is commonly used for surgery induced pain severity self-assessment.¹¹ In this study all patients had the same pain relief procedures in order to standardise the procedure for all the participants throughout.

Visual distraction is another economic beneficial modality that showed promising results, not only during cystoscopy but also with a variety of procedures performed under local anaesthesia.^{12, 13} Even though procedural pain was influenced in some patients watching the procedure on a separate monitor, not all studies showed a significant improvement in procedure related pain by watching the procedure.^{4, 5}

In our study we used a calming video with pleasant scenes of nature accompanied by relaxing music, as a distracting modality and the 11 point VAS to assess cystoscopy related pain. We found a mean VAS of $4.97 (\pm 1.35SD)$ in the non-intervention group, which is less than what Gupta *et al.*, found in their study with a

VAS of 7.12 ± 1.85 in their control group.¹⁴ We suspect the reasons for experiencing less pain in our study than the findings of Gupta *et al.*, (2019), might be that all procedures were done by one person, the standard local anaesthetic jelly dwell time was strictly adhered to, only adult males were included and all patients who had any type of intervention were excluded.

With this study, we confirmed the effectiveness of audiovisual distraction on pain during local rigid cystoscopy, since the pain was much less in the study group compared to the control group (Table 1). Similarly, Gupta *et al.*, and Gezginici *et al.*, both validated the superiority of audiovisual distraction over music only or visual distraction only, to relieve cystoscopy related pain.^{6, 14} Furthermore, Hudson *et al.*, in their meta-analysis, found that audiovisual distraction was efficacious in pain and anxiety management during surgery under local anaesthesia.¹⁵ However, conversely the validity of audiovisual distraction was questioned and not proven during an endovenous thermal ablation procedure.¹⁶

In addition, we found that age (>60years vs <60years) and/or previous cystoscopy experience are not factors that influence cystoscopy related pain (Table 1). On the other hand, Greenstein *et al.*, found that both age (>60years vs <60years) as well as previous cystoscopy experience were influencing factors on cystoscopy induced pain, ($P<0.001$) for both age and previous cystoscopy.²

Conclusion:

Many modalities of distraction during surgery under local anaesthesia, have shown a promising benefit in terms of pain and anxiety relief, but we confirmed in this study that AVD is a superior and reliable tool which decreases pain perception during local rigid cystoscopy under local anaesthetic. Therefore, AVD is thus highly recommended to be widely used in cystoscopy under local anaesthesia. Further

studies should be done using AVD in other types of surgeries under local anaesthesia, to investigate the potential pain relief in such other procedures.

Limitations:

The main limitations of this study are: that it was done in a single medical centre, more patient demographics could not be recorded due to the fairly small sample size for such a vast geographical area with a hugely varied population and also that the study period was of a limited duration.

Recommendations:

Another similar but longer study should be done at various medical facilities including more participants, in order to record and add patient demographics for meaningful statistical analyses.

A similar study as the abovementioned could be performed on female patients.

Similar studies using AVD should be used in other surgical procedures with local anaesthesia.

References:

1. Richard SM, John OD, Joshua JM. Cystoscopy. JAMA 2017; 317:1187.
2. Greenstein A, Senderovich S, Mabeesh NJ. Is Diagnostic Cystoscopy Painful? Analysis of 1,320 Consecutive Procedures. IBJU 2014; 40:533-38.
3. Seklehner S, Remzi M, Fajkovic H, Saratlija-Novakovic Z, Skopek M, Resch I, et al. Prospective multi-institutional study analyzing pain perception of flexible and rigid cystoscopy in men. Urology 2015; 85:737-41.
4. Patel AR, Jones JS, Angie S, Babineau D. Office Based Flexible Cystoscopy May be Less Painful for Men Allowed to View the Procedure. J Urol 2007; 177:1843-5.

5. Cornel EB, Oosterwijk E, Kiemeney L A. The effect on pain experienced by male patients of watching their office-based flexible cystoscopy. *BJU Int* 2008; 102:1445-6.
6. Gezginci E, Iyigun E, Kibar Y, Bedir, S. Three distraction methods for pain reduction during cystoscopy: A randomized controlled trial evaluating the effects on pain, anxiety and satisfaction. *J Endourol* 2018; 32(11):1078-1084.
7. Raheem OA, Mirheydar HS, Lee HJ, Patel Nishant D, Godebu E, Sakamoto K. Does Listening to Music During Office-Based Flexible Cystoscopy Decrease Anxiety in Patients, A Prospective Randomized Trial. *J Endourol* 2015; 29:791-6.
8. Suresh K. An overview of randomization techniques: An unbiased assessment of outcome in clinical research. *J Hum Reprod Sci* 2011;4(1):8-11.
9. Raja SN, Carr DB, Cohen M, Finnerup NB, Flor H, Gibson S, Keefe FJ, Mogil JS, Ringkamp M, Sluka KA, Song XJ, Stevens B, Sullivan MD, Tutelman PR, Ushida T, Vader K. The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. *Pain* 2020 Sep 1;161(9):1976-1982.
10. Yeung AWK, Wong NSM. The Historical Roots of Visual Analog Scale in Psychology as Revealed by Reference Publication Year Spectroscopy. *Front Hum Neurosci* 2019;13:86.
11. Reed MD, Van Nostran W. Assessing pain intensity with the visual analog scale: a plea for uniformity. *J Clin Pharmacol* 2014 Mar;54(3):241-4
12. Choudhury N, Amer I, Daniels M, Wareing MJ. Audiovisual distraction reduces pain perception during aural microsuction. *Ann R Coll Surg Engl* 2013; 95:34-36.
13. Carwile JL, Feldman S, Johnson NR. Use of a Simple Visual Distraction to Reduce Pain and Anxiety in Patients Undergoing Colposcopy. *J Low Genit Tract Dis* 2014; 18:317-21.

14. Gupta S, Das SK, Jana D, Pal DK. Distraction during cystoscopy to reduce pain and increase satisfaction: Randomized control study between real-time visualization versus listening to music versus combined music and real-time visualization. Urol Ann 2019 Jan-Mar;11(1):33-38.
15. Hudson BF, Ogden J. Exploring the Impact of Intraoperative Interventions for Pain and Anxiety Management During Local Anesthetic Surgery-A Systematic Review and Meta-Analysis. J Perianesth Nurs 2016 Apr;31(2):118-33.
16. Zandvoort CE, Toonder IM, Stoopendaal IA, Wittens CH. The effect of distraction on pain perception during an endovenous thermal ablation procedure. Phlebology 2016; 31:463-70.

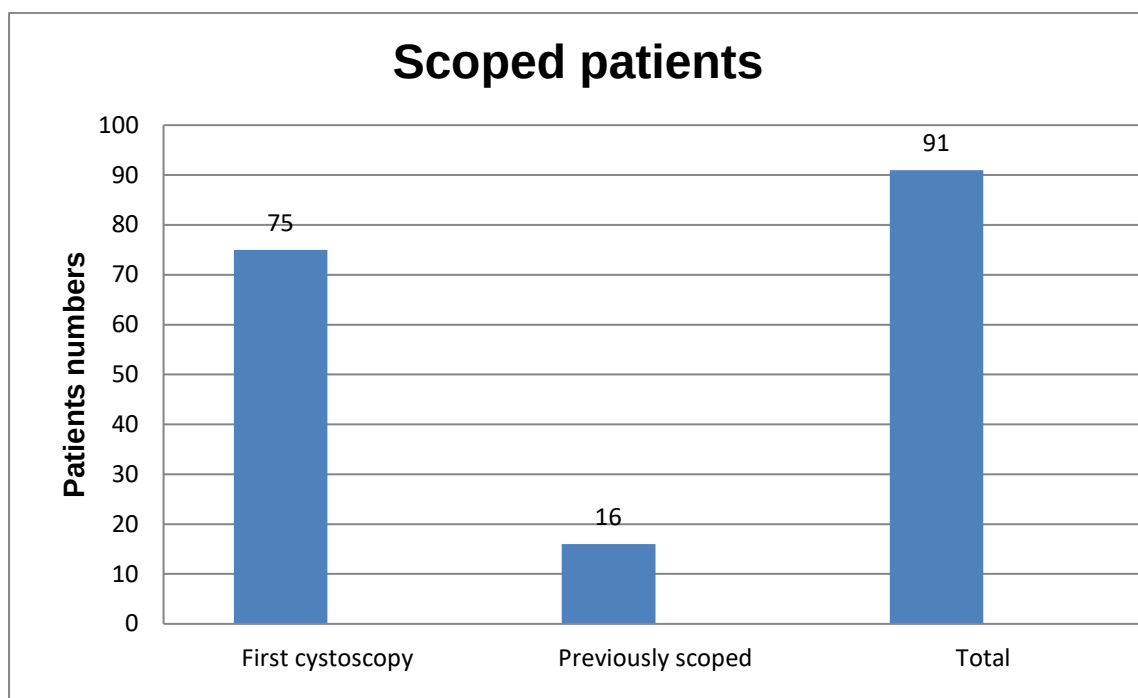


Figure1: Patients who had cystoscopies

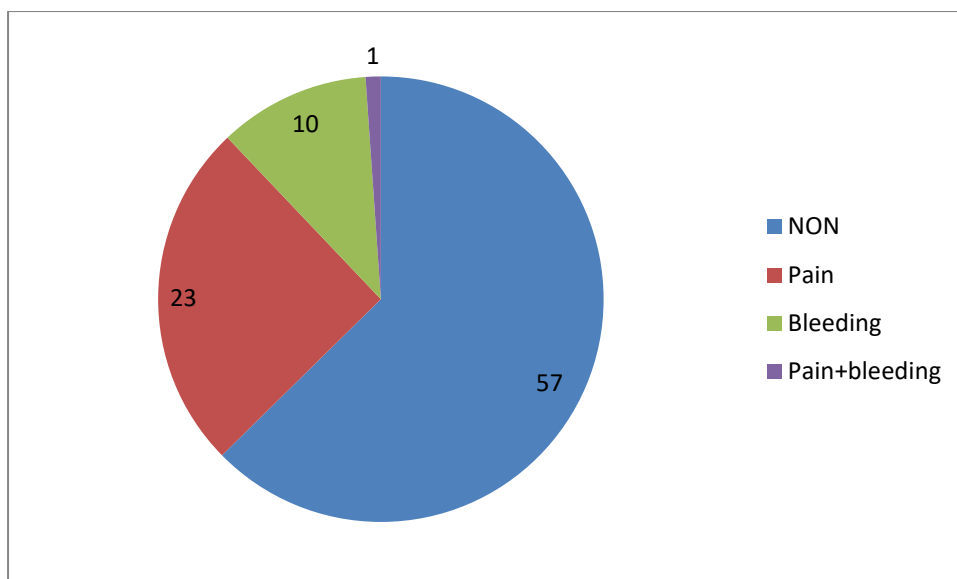


Figure 2: Numbers of early complications post-cystoscopy.

Table 1: Comparison of pain levels during cystoscopy related to previous procedures

Variables	Study group VAS $\pm$ SD	Control group VAS $\pm$ SD	P value
Previously scoped	2.6($\pm$ 1.32)	4.42($\pm$ 1.27)	0.008
No previously scoped	2.4($\pm$ 1.18)	5.08($\pm$ 1.38)	<0.001
P value	0.35	0.14	

Data presented as mean (SD). Comparisons done using Mann-Whitney comparisons

Appendices:

Appendix I: Submitted and approved protocol

ATTACHED IS THE ORIGINAL RESEARCH PROTOCOL AS APPROVED BY THE ASSESSORS' COMMITTEE AND SUBSEQUENTLY SUBMITTED TO POSTGRADUATE OFFICE IN ITS FINAL FORM AS BELOW.

AVD DURING CYSTOSCOPY | 2010

Pain modulation by audiovisual distraction during local cystoscopy

MMED Research Protocol

Department of Surgery, Division of Urology

Dr Amadadin Alhlib
Student number: 1304354

Supervisors:

1. Prof. M Haffejee
MBBCH, FCS (Urology) SA
Head of Urology WITS University
Email: mohamedhaffejee@mweb.co.za
Phone: 082 365 0030
2. Dr Marietha Nel
BSc, BScHon(Pharmacol), MSc, PhD
Senior Scientist
Department of Surgery, WITS University
Email: marietha.nel@wits.ac.za
Phone: 079 858 5690

1

Introduction and literature review:

Cystoscopy is one of the most common urological procedures used for either diagnostics, therapeutics or for surveillance. It may be performed under local or under general anaesthesia. It is indicated for patients who present with haematuria, recurrent urinary tract infection, and lower urinary tract symptoms or for surveillance after urinary bladder tumour resection. The local cystoscopy is performed in the lithotomy or supine position. After application of the local anaesthetic, 2% remicaine jelly, the procedure is commenced by introducing the scope through the urethra while inspecting the route into the bladder, using irrigation to achieve better visualisation. The procedure is associated with pain and discomfort, whether it is performed using a flexible or a rigid scope. The procedural induced pain, is due to navigation through the urethra and from bladder extension. The aim of the procedure is to visually inspect the lower urinary tract urethra, prostate and urinary bladder. The procedure may be complicated by dysuria, haematuria or symptoms of urinary tract infection.¹

Despite only taking a few minutes the procedure can be so uncomfortable that sometimes the patient refuses to proceed or having a re-scope in future. Greenstien *et al.*, (2014) evaluated 1320 patients who underwent diagnostic local cystoscopy and showed a higher pain level following a first-time scope than in a repeated scope (Visual Analogue Scale (VSA) 2.8 ± 1.6 , SD 2.2 ± 1.4 , $p < 0.001$).²

Many studies have been performed to understand the severity of pain during local cystoscopy and to try and make it more pleasant for the patients. In a prospective multi-institutional study 300 cystoscopies were done, 150 were rigid cystoscopies and the other 150 were flexible

cystoscopy. The results showed that flexible cystoscopy inflicts less pain on men who had the procedure for the first time, while not influencing the pain sensation in the patients who had the experience previously, hence the type of the scope is an independent risk factor for pain perception.³ In another study, the effectiveness of 2% lignocaine jelly was compared to aquagel which is a water based jelly. The patients were divided into two groups, the first group's cystoscopy started 15minutes after application of 2% lignocaine jelly while the second group's cystoscopy started directly after aquagel jelly was smeared around the scope and in the urethra. In both groups the VAS pain score was 3 or less, and there was no significant difference between the groups in terms of pain control.⁴ Importantly, the lignocaine increased the procedure duration, effort and cost with no beneficial effect.

In 2013 a prospective controlled study was done to describe the severity of rigid cystoscopy induced pain and to compare it to urodynamic tests induced pain in women. One hundred and nine women were involved, of which 57 underwent cystoscopy and the others underwent urodynamic tests. The cystoscopy was found to produce more pain (VAS 1.9 ± 1.8) than urodynamics (VAS 1.2 ± 1.6). However, patients anticipated both procedures to be more painful than they actually are.⁵

Pawan *et al.* (2014) performed a prospective randomised study to clarify the optimum intra-urethral dwell time of 2% lidocaine jelly for pain relief during outpatient rigid cystoscopy. Four hundred patients were randomised into four groups (A, B, C, D) according to the procedure starting time of 5, 10, 15 or 20 minutes respectively, after 2% lidocaine jelly application. The study showed that 15 minutes before the procedure is the best time to apply 20ml of 2% lidocaine jelly.⁶

The effect of audio-stimulation on the procedural pain and anxiety has also been studied. For this prospective randomised trial the study question was: Does listening to music during office based flexible cystoscopy decrease anxiety and pain in patients? A total of 137 patients were randomised to either have office based flexible cystoscopy with (73) or without (64) music. Music was shown to reduce both the pain and the anxiety in patients undergoing cystoscopy, as well as the patient's discomfort and dissatisfaction with the procedure.^{7, 8}

Furthermore, researchers also investigated whether the pain would be reduced if the patient could watch their own procedure being performed. Of the two studies available in the literature, one such study showed a 40% reduction in pain, while the second study showed no effect on the perception of pain.^{9, 10}

Audiovisual distraction has been tried by different medical disciplines. For example, a total of 37 patients participated in a study to demonstrate the effect of audiovisual distraction on the patient's pain perception during aural microsuction. The patients watched their own microsuction procedure of one ear on a television screen, while they did not view the microsuction procedure on the other ear. The mean VAS pain score for the viewed side was 2.43 vs 3.48 on the other side ($p=0.003$). The effect of audiovisual distraction on pain and anxiety during aural microsuction showed that the audiovisual distraction significantly reduced the pain perception during the procedure.¹¹

Additionally, the effect of passive visual distraction on pain and anxiety was tested on women who had colposcopy procedures at the Brigham- and the Women's Hospital Colposcopy Clinics. In this study, visual distraction decreased the perception of pain but it did not affect the patient's anxiety during colposcopy.¹²

Conversely, audiovisual distraction did not significantly reduce the perceived pain during an endo-venous thermal ablation under tumescent anaesthesia. In this study the patients were randomised into two groups: not distracted (-AVD) and distracted (+AVD). According to the VAS pain score, the distracted group's pain score was 2.6 (SD $\pm$ 2.3) vs 2.85 (SD $\pm$ 1.7) for the non-distracted group. There was not a statistically significant difference between the two groups ($p=0.68$).¹³

Study rationale:

There is currently no data in South Africa in this field of AVD during cystoscopy, therefore, this study will be the first in our institution and thus in South Africa.

Study aim:

The aim of this study is to determine the level of pain during local rigid cystoscopy on adult male patients. This study further aims to demonstrate the effect of audiovisual distraction on pain perception during local rigid cystoscopy.

Study objectives:

1. To describe the level of perceived pain during cystoscopy
2. To compare the levels of perceived pain during cystoscopy with and without AVD during local cystoscopy at CMJAH.

Methods:

The study will be performed at the Charlotte Maxeke Johannesburg Academic Hospital in the local cystoscopy theatre of the Urology Division. Patients will be exposed to a distracting musical video during the local rigid cystoscopy procedure. As already well known, the human brain responds to a super-threshold stimulus and neglects the weaker stimulus. Therefore, we aim to do our cystoscopy procedure with as little pain as possible, with less anxiety and less dissatisfaction to the patient, while maintaining good quality scopes.

Study design:

This will be a prospective randomised controlled study.

Study location:

The study will be performed in the urology minor theatre rooms at CMJAH.

Study population:

Adult male patients requiring routine cystoscopy procedures.

Inclusion criteria:

All adult male patients over the age of 18 years, without any of the exclusion criteria, already booked for diagnostic local cystoscopy.

Exclusion criteria:

Patients with poor vision or blindness

Patients hard of hearing or deaf

Patients who are mentally challenged

Patients with spinal cord injury or any other sensory deficits of the perineum

Patients who are having any form of intervention during the scope, including optical urethrotomy, biopsy or double J stent removal

Sample size:

The planned study will comprise of two groups: A control group and a study group, each comprising at least 50 patients with a maximum of 120 patients. The estimated duration is six months.

Procedure:

Male patients without any of the exclusion criteria, requiring routine cystoscopy will be counselled before the procedure. Each patient will be given an information sheet and only once consent has been given and signed, each patient will choose a piece of white paper with a letter C or S to allocate him to one of the two groups (control or study). Patients will thus be randomly distributed into two groups: the first group will have the procedure done under the current conditions without AVD (control group) and the second group will watch a video clip with music (time lapse with sunsets, cloud and stars) on a tablet during the procedure (study/test group).

The patients will be taken to the procedure room, placed in the lithotomy position, cleaned with savlon solution if he is not allergic to it. The procedure will commence 15 minutes after applying 2% remicaine jelly in the urethra of all patients regardless of the group (control or test). Normal saline will be used for irrigation and bladder over-distension will be avoided. The bladder will be emptied at the end of the procedure and an oral analgesic (Painblock

tablets) will be prescribed if indicated. The cystoscopy procedure will be done by the same doctor (the PI researcher). Approximately 15 minutes (time to dress) after the procedure each patient (in a private room) will fill in a questionnaire which includes the patient study number, demography and the pain score according to VAS (Appendix 1). Every point in the questionnaire will be explained if necessary and the contact details of the PI researcher will be given for further explanations or for follow-ups in terms of procedural induced pain, or in case of haematuria. Furthermore, the doctor (PI researcher) will at the same time but in a separate office, fill in another questionnaire (Appendix 2), describing the details of the procedure.

Data analysis:

The collected questionnaire data will be entered into an excel spread sheet. Descriptive statistics will be done using percentages for categorical data, mean and standard deviation or median and range for normally distributed or skewed data respectively. The comparison between pain levels will be done using a Mann Whitney U test for non-parametric data. A p-value of <0.05 will be considered to be statistically significant.

Ethics:

Patient's personal details will be kept confidential and a specific study number will be allocated to each individual patient. This number will be placed on the questionnaires and the link to personal information will be kept separate. Every patient will be counselled and consented privately before entering the study. Permission will be obtained in writing from the HOD of the Urology Division at CMJAH and from the CEO of the CMJAH. The study will only commence after these permission and the approval of the Human Research Ethics

Committee (HERC) (medical) of the University of the Witwatersrand have been obtained and the study been allocated a HERC number.

Funding:

The stationary and photocopying needed for the study will be supplied and paid for by the PI. No additional funding will be needed for this study.

Problems:

At present there are no anticipated problems which might affect the study.

Time table:

2018/19	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Literature review												
Preparing Protocol												
Protocol assessment												
Ethics Application												
Collecting Data												
Data												

analysis												
Writing up-thesis												
Writing up-paper												

References:

1. Richard SM, John OD, Joshua JM. Cystoscopy. *JAMA* 2017; 317(11):1187.
2. Greenstein A, Greenstein, Senderovich S, Mabjeesh NJ. Is Diagnostic Cystoscopy Painful? Analysis of 1,320 Consecutive Procedures. *International Brazilian Journal of Urology* 2014; 40(4):533-38
3. Seklehner S, Remzi M, Fajkovic H, Saratlija-Novakovic Z, Skopek M, Resch I, Duvnjak M, Hruba S, Librenjak D, Hübner W, Breinl E, Riedl C, Engelhardt PF. Prospective multi-institutional study analyzing pain perception of flexible and rigid cystoscopy in men. *Urology* 2015; 85(4):737-41.
4. Palit V, Ashurst HN, Biyani CS, Elmasray Y, Puri R, Shah T. Is Using Lignocaine Gel prior to Flexible Cystoscopy Justified? *Urologia Internationalis* 2003; 71(4):389-92.
5. Yerlikaya G, Laml T, Elenskaia K, Hanzal E, Kölbl H, Umek W. Pain perception during outpatient cystoscopy: a prospective controlled study. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 2014; 173:101–105.

6. Pawan V, Anup K, Niraj K, Sanjeev K J, Rohit K, Avijit M, Biswajit N, Harbinder S. Effect of Intraurethral Dwell Time of Local Anesthetic Jelly on Pain Perception in Men Undergoing Outpatient Rigid . *Journal of Endourology* 2014; 28(7):846-9.
7. Raheem OA, Mirheydar HS, Lee HJ, Patel Nishant D, Godebu E, Sakamoto K. Does Listening to Music During Office-Based Flexible Cystoscopy Decrease Anxiety in Patients, A Prospective Randomized Trial. *Journal of Endourology* 2015; 29(7):791-6.
8. Yeo JK, Cho DY, Oh MM, Park SS, Park MG. Listening to Music During Cystoscopy Decreases Anxiety, Pain, and Dissatisfaction in Patients: A Pilot Randomized Controlled Trial. *Journal of Endourology* 2013; 27(4):459-62.
9. Cornel EB, Oosterwijk E, Kiemeny L A. The effect on pain experienced by male patients of watching their office-based flexible cystoscopy. *BJU International* 2008; 102(10):1445-6.
10. Patel AR, Jones JS, Angie S, Babineau D. Office Based Flexible Cystoscopy May be Less Painful for Men Allowed to View the Procedure. *Journal of Urology* 2007; 177(5):1843-5.
11. N Choudhury, I Amer, M Daniels, MJ Wareing. Audiovisual distraction reduces pain perception during aural microsuction. *Annals of the Royal College of Surgeons of England* 2013; 95(1):34-36.
12. Carwile JL, Feldman S, Johnson NR. Use of a Simple Visual Distraction to Reduce Pain and Anxiety in Patients Undergoing Colposcopy. *Journal of Lower Genital Tract Disease* 2014; 18(4):317-21.

13. Zandvoort CE, Toonder IM, Stoopendaal IA, Wittens CH. The effect of distraction on pain perception during an endovenous thermal ablation procedure. *Journal of Venous Disease* 2016; 31(7):463-70.

Appendix II: Approval of research protocol



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

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

13 November 2018
Person No: 1304354
PAG

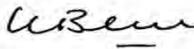
Dr A Alhlib
13 Positano
Pranticole Avenue
Allens Neck
1709
South Africa

Dear Dr Amadadin Alhlib

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Pain modulation by audiovisual distraction during local cystoscopy* 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

Appendix III: Patient's questionnaire

[Type text]



AVD study **patientquestionnaire**

➤ Would you please fill in the following information , you are welcome to ask for further explanation

➤ Demographics:

Patient serial number:

Age: yr

➤ Procedure details:

First time ☐ had it before ☐

If not first time, please describe the pain in the last one

➤ Needs for analgesic: yes ☐ No ☐

[Type text]



➤ Problems developed after :Yes ☐ No ☐
if yes please specify

➤ Visual analogue pain scale:

Please circle one number according to your pain severity.

00	01	02	03	04	05	06	07	08	09	10
----	----	----	----	----	----	----	----	----	----	----

➤ Extra note:

.....

.....

.....

..

Date : / /20

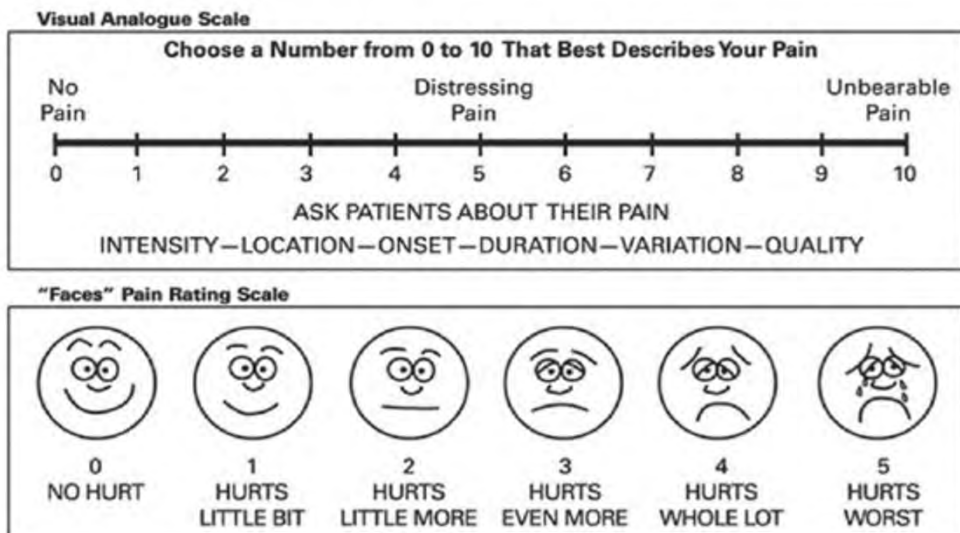
Patient signature:

[Type text]



Please ask the doctor to assist with the meaning of the pictures below.

Figures: Tools Commonly Used to Rate Pain





AVD study doctor questionnaire

- Patient serial number:
- Randomised group: S ☐ C ☐
- Procedure note :

- Exclusion criteria: yes ☐ no ☐
- If yes please specify



➤ Complication :

Date : / /20

doctor signature:

Appendix V: Ethics clearance certificate



R14/49 Dr Amadadin Alhlib

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M180817

NAME: Dr Amadadin Alhlib
(Principal Investigator)
DEPARTMENT: Surgery
Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE: Pain modulation by audiovisual distraction during local cystoscopy
DATE CONSIDERED: 31/08/2018
DECISION: Approved Unconditionally
CONDITIONS:
SUPERVISOR: Dr Marieta Nel
APPROVED BY: 
Doctor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL: 01/02/2019

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. 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 resubmit the application to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **August** and will therefore be due in the month of **August** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).


Principal Investigator Signature

15/07/2020
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix VI: Turnitin report

a0046051:Alhlib_FINAL_FINAL_MMed_report_TIN.docx

ORIGINALITY REPORT

7 %	7 %	2 %	3 %
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	worldwidescience.org Internet Source	1 %
2	www.coursehero.com Internet Source	1 %
3	journalarticle.ukm.my Internet Source	1 %
4	theses.gla.ac.uk Internet Source	1 %
5	encore.lib.gla.ac.uk Internet Source	1 %
6	www.em-consulte.com Internet Source	1 %
7	www.deepdyve.com Internet Source	<1 %
8	rba.elsevier.es Internet Source	<1 %
9	www.nature.com Internet Source	<1 %
10	patient.info Internet Source	<1 %
11	K E Hodgkinson, J N Mahlangu. "Deep-vein thrombosis in the era of high HIV and tuberculosis prevalence: A prospective review of its diagnosis and treatment in a quaternary centre", South African Medical Journal, 2017 Publication	<1 %

Exclude quotes

On

Exclude matches

< 5 words

Exclude bibliography

On

Appendix VII: Copy of published article in Annals of Urology

[Downloaded free from <http://www.urologyannals.com> on Tuesday, April 13, 2021, IP: 197.185.108.40]

Original Article

Pain modulation by audiovisual distraction during cystoscopy

Amadadin R. Alhlib, Mohamed Haffeejee, Marietha J. Nel

Department of Surgery, Division of Urology, Faculty of Health Sciences, Medical School, University of the Witwatersrand, Johannesburg, South Africa

Abstract

Introduction: Cystoscopy is one of the most common urological procedures used for either diagnostics, therapeutics, or for surveillance. It may be performed under local or general anesthesia. The procedure is associated with pain and discomfort.

Aims: The aim of the study was to compare the levels of perceived pain during local cystoscopy with and without audiovisual distraction (AVD).

Methodology: A randomized control study was performed at our academic hospital local cystoscopy theater of the urology division. Approximately half the patients already booked for the local rigid cystoscopy procedure were exposed to a distracting musical video during the procedure (study group), while the control group was not.

Statistical Analysis: Descriptive statistics were used to determine percentage, mean, and standard deviation (SD) for categorical data. The Mann–Whitney U-test for nonparametric data was used for comparing pain levels.

Results: A total of 91 patients participated in the study with 48 patients in the study group and 43 patients in the control group. The visual analog scale (VAS) ranged between 1 and 5/10 in the study group and 1–8/10 in the control group, while the mean VAS was 2.52 ± 1.2 SD in the study group and 4.97 ± 1.35 SD in the control group. The AVD intervention was statistically significant ($P < 0.0001$).

Conclusion: AVD during local rigid cystoscopy is highly recommended, especially in patients undergoing the procedure for the first time.

Keywords: Audiovisual distraction, cystoscopy-induced pain, cystoscopy

Address for correspondence: Dr. Amadadin R. Alhlib, 1 Perth Road Westdene Johannesburg 2092, South Africa.
E-mail: halipo2020@gmail.com

Received: 23.06.2020, **Accepted:** 04.03.2021, **Published:** 13.04.2021

INTRODUCTION

Cystoscopy is associated with pain,^[1] with first-time patients experiencing a higher pain level than in a repeated scope ($P < 0.001$).^[2] Although flexible cystoscopy inflicts less pain than rigid scoping on first-time scope men, it

did not cause less pain in patients who had the procedure previously.^[3]

Types of distraction to aid in pain relief during cystoscopy procedures is controversial. In one study where patients watched their own procedure, a 40% pain reduction was

Access this article online	
Quick Response Code:	Website: www.urologyannals.com
	DOI: 10.4103/UA.UA_104_20

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: WKHLRPMedknow_reprints@wolterskluwer.com

How to cite this article: Alhlib AR, Haffeejee M, Nel MJ. Pain modulation by audiovisual distraction during cystoscopy. *Urol Ann* 2021;13:163-5.

shown,^[4] while another study showed no effect.^[5] Music, video, or stress ball distractions decreased pain during rigid cystoscopy,^[6] and audiotimulation reduced pain during flexible cystoscopy.^[7]

Study rationale

There is currently no data in South Africa on the effect of audiovisual distraction (AVD) during cystoscopy. Therefore, this study is not only the first in our institution but also in the country.

Study aim

The aim of this study was to determine the level of pain and to demonstrate the effect of AVD on pain perception during local rigid cystoscopy in adult male patients.

Study objectives

The study objectives were to describe the level of perceived pain and to compare the levels of perceived pain during local rigid cystoscopy with and without AVD.

METHODOLOGY

Sample population

Adult male patients (91) over the age of 18 years, without any of the exclusion criteria (poor vision or blindness, hard of hearing or deaf, mentally challenged, spinal cord injury or any other sensory deficits of the perineum, any form of intervention during the scope including optical urethrotomy, biopsy or double J stent removal, and patients refusing participation in the study) but already booked for diagnostic local cystoscopy were included in the study.

Procedure

The effect of AVD on pain during rigid cystoscopy was determined by testing the VAS pain level in both the study and in the control group. This single-center randomized control study was designed to illustrate the significance of AVD intervention. A questionnaire was designed for the patients to describe their experience after the procedure.

Data was statistically analyzed to express the VAS pain level of each group and to determine the difference between the two groups.

All 91 patients were counseled before the procedure, given an information sheet and only once consent was given and signed, and each patient randomly chose a piece of white paper with either the letter C or S, to allocate patients to one of the two groups (control or study group). Patients were thus randomly distributed into two groups: The first group had the procedure done under the current conditions without AVD (control group), while the second group

watched a video clip with music (time lapse with sunsets, clouds, and stars) on a tablet during the procedure (test group).

The patients were placed in the lithotomy position, cleaned with Savlon solution if not allergic, or otherwise either betadine or normal saline was used. The procedure commenced 15 min after applying 2% Remicaine jelly in the urethra of all patients (control and test).^[8] Normal saline was used for irrigation and bladder overdistension was avoided. The bladder was emptied at the end of the procedure and an oral analgesic (painblock tablets) was prescribed if so indicated. All the cystoscopy procedures were done by the principal investigator. Approximately 15 min (time to dress) after the procedure each patient (in a private room) filled in a questionnaire.

Data analysis

The collected questionnaire data was entered into a Microsoft Excel spreadsheet. The STATA Version 14.2 (College Station, TX, USA) statistical software package was used to analyze the collected data. Descriptive statistics for categorical data using percentage, mean, and standard deviation (SD) for normally or median and range for skew distributed data were done. The Mann-Whitney U-test for nonparametric data was used to compare the pain levels. $P < 0.05$ was considered to be statistically significant.

RESULTS

A total of 16 (17.6%) patients had been scoped before and attended the clinic for follow-up cystoscopy [Figure 1].

Age was not considered an important factor in cystoscopy with or without AVD and was not statistically significant ($P = 0.17$).

VAS ranged between 1 and 5/10 in the study group and between 1 and 8/10 in the control group, while the mean VAS was (2.52 ± 1.2 SD) in the study group and (4.97 ± 1.35 SD)

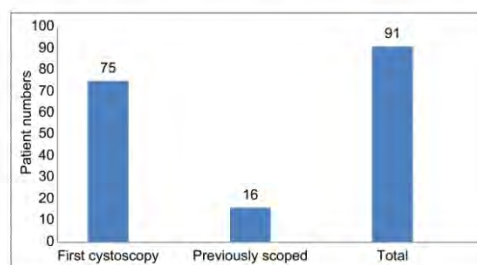


Figure 1: Patients who had cystoscopies

in the control group. The AVD intervention was statistically significant ($P = 0.000$) [Table 1].

Early complications after the cystoscopy procedure were also determined: 57 patients (62.6%) did not have any early complications, while 23 patients (25.2%) suffered from pain after the procedure, 10 patients (10.9%) had urethral bleeding, and one patient (1.1%) had both pain and urethral bleeding [Figure 2].

DISCUSSION

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage as per the International Association for the Study of Pain. VAS is a pain measurement tool, which is validated for the measurement of acute pain.^[9]

Many measures are used to decrease pain perception during cystoscopy, such as the scope sheet size and using a flexible scope instead of rigid, but were found independent factors affecting pain level.^[3] However, introducing 2% lidocaine intra-urethral jelly 15 min before the procedure significantly decreased pain.^[6] Listening to music was associated with less pain during cystoscopy and less sedation (midazolam) was needed during colonoscopy.^[7,10,11]

Patients who have transurethral catheters for any reason experienced less pain and were more comfortable during the procedure than patients without chronic transurethral catheters. Four patients had chronic transurethral catheters,

three were in the study group and one in the control group. All four patients had a VAS of one.

CONCLUSION

In this study, AVD is confirmed to be a reliable tool to decrease pain perception during local rigid cystoscopy under local anesthesia and is thus highly recommended, especially in patients who are undergoing the procedure for the first time.

Acknowledgment

The study was performed at Charlotte Maxeke Johannesburg Academic Hospital. Special thanks to Prof A Adam and all Urology Department doctors and nurses.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

- Matulewicz RS, DeLancey JO, Meeks JJ. Cystoscopy. JAMA 2017;317:1187.
- Greenstein A, Greenstein I, Senderovich S, Mabeesh NJ. Is diagnostic cystoscopy painful? Analysis of 1,320 consecutive procedures. Int Braz J Urol 2014;40:533-8.
- Seklehner S, Remzi M, Fajkovic H, Saratija-Novakovic Z, Skopek M, Resch I, et al. Prospective multi-institutional study analyzing pain perception of flexible and rigid cystoscopy in men. Urology 2015;85:737-41.
- Cornel EB, Oosterwijk E, Kiemeny LA. The effect on pain experienced by male patients of watching their office-based flexible cystoscopy. BJU Int 2008;102:1445-6.
- Patel AR, Jones JS, Angie S, Babineau D. Office based flexible cystoscopy may be less painful for men allowed to view the procedure. J Urol 2007;177:1843-5.
- Gezginci E, Iyigun E, Kibar Y, Bedir S. Three distraction methods for pain reduction during cystoscopy: A randomized controlled trial evaluating the effects on pain, anxiety, and satisfaction. J Endourol 2018;32:1078-84.
- Raheem OA, Mirheydar HS, Lee HJ, Patel ND, Godebu E, Sakamoto K. Does listening to music during office-based flexible cystoscopy decrease anxiety in patients: A prospective randomized trial. J Endourol 2015;29:791-6.
- Vasudeva P, Kumar A, Kumar N, Jha SK, Kumar R, Mohanty A, et al. Effect of intraurethral dwell time of local anesthetic jelly on pain perception in men undergoing outpatient rigid cystoscopy: A randomized prospective study. J Endourol 2014;28:846-9.
- Bijur PE, Silver W, Gallagher EJ. Reliability of the visual analog scale for measurement of acute pain. Acad Emerg Med 2001;8:1153-7.
- Yeo JK, Cho DY, Oh MM, Park SS, Park MG. Listening to music during cystoscopy decreases anxiety, pain, and dissatisfaction in patients: A pilot randomized controlled trial. J Endourol 2013;27:459-62.
- Harikumar R, Raj M, Paul A, Harish K, Kumar SK, Sandesh K, et al. Listening to music decreases need for sedative medication during colonoscopy: A randomized, controlled trial. Indian J Gastroenterol 2006;25:3-5.

Table 1: Mean visual analog scale and P values for study and control groups

	Study group VAS	Control group VAS	P
Mean±SD	2.52±1.20	4.97±1.35	<0.001

VAS: Visual analog scale, SD: Standard deviation

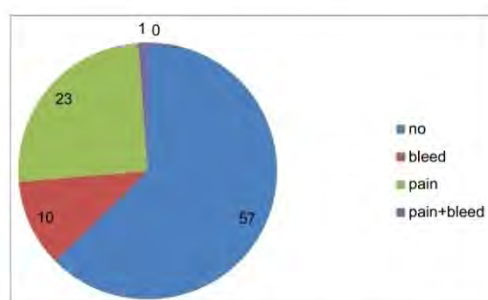


Figure 2: Numbers of early complications post cystoscopy